Knowledge Creation in Corporate Research and Development: An Investigation into the Approaches and Practices employed within the Pharmaceutical Industry in the United Kingdom at the start of the 21st Century

Thesis

Knowledge Creation in Corporate Research and Development

An Investigation into the Approaches and Practices employed within the Pharmaceutical Industry in the United Kingdom at the start of the 21st Century

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ABSTRACT

Throughout the development of corporate R&D, there has been a search for the 'one best way' to manage the processes involved. Although perceptions of what constitutes the 'one best way' have changed over time, the quest for reliable pointers continues. This thesis develops the author's personal interest in how things 'ought to be' in order to secure success within corporate R&D. Marrying ideas from the fields of R&D Management and Knowledge Management, and using the results from an empirical study into pharmaceutical R&D in the United Kingdom, the thesis shows the distinct differences between knowledge creation in research and knowledge creation in development and concludes that these two activities should be carried out separately, but not separate from each other.

In arriving at this conclusion, the thesis upholds the criticisms of the knowledge creation model advocated by Nonaka and Takeuchi (1995); and points to the failings of the pluralist framework proposed by Cook and Brown (1999); arguing, after Polanyi (1966), that knowledge creation in any context is better modelled with reference to the individual acts of tacit knowing of the particular people involved, acts of tacit knowing which lead to the subsidiary conclusion that research should remain a scientific endeavour, whereas development should be a transdisciplinary, transfunctional, and perhaps a trans-organizational activity. Hence, the thesis rejects the trends in R&D generations reported in the R&D Management literature; and the corresponding move from a Mode 1 to a Mode 2 approach predicted by Gibbons and co-workers in the Knowledge Management literature.

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1 INTRODUCTION

1.1 Background to the Research and the Research Question

Throughout the development of corporate R&D, there has been a search for the 'one best way' to manage the processes involved. Although perceptions of what constitutes the 'one best way' have changed over time, the quest for reliable pointers continues. This thesis develops the author's personal interest in how things 'ought to be' in order to secure success within corporate R&D.[1] It presents the progression from a comparatively simple research question to more complex conceptual issues, together with the design and implementation of original empirical work.

Over the years, success in corporate R&D has been associated with a number of factors: the right organizational configuration (Mintzberg, 1979, p.217); the right people (Roberts and Fusfeld, 1981, p.19); the right vision or strategy (Quinn, 1985, p.266); the right climate (Ekvall, 1991, p.73) or culture (Kanter *et al*, 1997, p.4; Tang, 1998, p.304); a fit between managerial approach and the stability of the technical and market environments (Burns and Stalker, 1961, p.96); a fit between process and corporate strategy (Maidique and Patch, 1978, p.248); or a fit between market and technology (Abernathy and Clark, 1985, p.5). More recently, success in corporate R&D has been linked to a fit between R&D approach and the prevailing commercial environment (Utterback, 1994, p.viii; Kumpe and Bolwijn,

[1] It should perhaps be noted here that the present author hails from a corporate R&D background in the chemical industry. Hence, the references made within this thesis to 'experience'. However, it should also be noted that it was the intention that any discussion or theories expressed within this thesis would be grounded in the findings of this current study, and would not be assumed from this past experience.

1994; Varma, 1995; Rogers, 1996; Ahmed, 1998; Liyanage *et al,* 1999), a commercial environment that is currently treating 'knowledge' as a source of advantage (see, for example, Jordan and Jones, 1997, p.392; Brown and Duguid, 1998, p.91; Coles, 1999, p.61; McAdam and McCreedy, 1999, p.91; Smart *et al*, 1999, p.110; McElroy, 2000, p.199) and the management of that knowledge as the competence of interest (for example, Stewart, 1997, p.xii; Quintas *et al,* 1997, p.385; Davenport, 1997, p.178; Inkpen and Dinur, 1998, p.454; Madhaven and Grover, 1998, p.1; Ruggles, 1998, p.80; Despres and Chauvel, 1999, p.110; Rickards and Moger, 1999, p.67; Smith, 2000, p.305; Armbrecht *et al,* 2001, p.28; Coates, 2001, p.9; Hansen and von Oetinger, 2001, p.106;.Parikh, 2001, p.27).

The importance of knowledge, particularly scientific and technical knowledge, to effective human activity, and, indeed to the good of society in general, has been recognized for many years. For example, whether fact or fiction, and whatever the moral lessons that may or may not have been intended, Plato's *Timaeus* and *Critias* (circa 348 BC) both tell the story of the ultimate defeat of the invading armies from 'Atlantis' by the more skilful and technologically advanced army of ancient Athens (Lee, 1965, p.36; Galanopoulos and Bacon, 1969, p.175). Over one and a half millennia later in 1605, in *The Advancement of Learning,* Francis Bacon also advocated the importance of scientific knowledge to human progression (Bacon, World Classics Edition, 1906, p.39), a theme that he developed in *New Atlantis* in 1623, in his description of a society which is ruled by a knowledge elite that drives civilization forward through the pursuit and application of scientific knowledge (ibid, p.296). More recently, scientific and technical knowledge has been seen, more specifically, as the harbinger of not only economic wealth but also the very survival of nations. For example, in 1935, Joseph Schumpeter advanced the opinion that scientific and technological innovations (or the effective application of new scientific and technical

knowledge) were important factors in determining the economic changes associated with the 'business-cycle' (Schumpeter, 1935, p.7). Later, in the *Age of Discontinuity*, Peter Drucker stressed the importance of theoretical and systemic knowledge (that is, scientific knowledge) as the crucial resource of the economy (Drucker, 1969, p.ix). And, in *Science Since Babylon,* Derek de Solla Price suggested that the prosperity and survival of nations in the modern world depended on their prowess in science and technology (de Solla Price, 1975, p.118).

Since the mid 1970s business organizations in general have seriously begun to take account of the knowledge available to them, producing supplementary annual reports reflecting the intellectual capital that they own, employing balanced scorecard performance plans to try and capture and expand upon the value of their intangible assets, and employing chief knowledge officers to improve their processes for knowledge generation and application (Ruggles, 1997, p.1). To some extent, organizations have therefore adopted the view that their economic and producing power lies as much in their intellectual capabilities as in their hard assets such as land, plant, and equipment (Quinn, 1992, p.241). One notable account of how these intellectual capabilities might be managed in order to gain a competitive edge in the twenty-first century is Thomas Stewart's book: *The Wealth of Knowledge* (Stewart, 2002, p.123).

With the recognition that knowledge, and particularly scientific and technical knowledge is important to the economic welfare of organizations, we might perhaps question why the benefits expected from this 'knowledge environment' have not, in general, materialized within corporate R&D in the United Kingdom (UK). Based on the assumption made by many organizations and some academics that knowledge would flow freely across

cyberspace, these benefits included the reduction of internal costs by the removal of duplicate and non-core activities, and the acquisition of new knowledge as and when required. However, rather than the efficient and effective use of knowledge expected from these approaches, companies have found that many of the skills and much of the knowledge upon which their organizations were and are based are no longer available to them or are no longer accessible by them. What was not realized, and what will be shown later in this thesis, is that knowledge is not a 'commodity' that can be bought and sold or an 'asset' that can be managed in the traditional sense, but is something that is inherently personal and context dependent (Winter, 1987, p.160). As a consequence, the effective application of knowledge relies on the active participation of the people holding that knowledge in the particular activities being undertaken. As will also be shown later, success in contemporary corporate R&D then ultimately becomes dependent upon the interaction between approaches to R&D and evolving 'needs' associated with the activity being pursued.

Adopting a knowledge perspective, this thesis makes the assumption that the underlying purpose of corporate R&D is the creation of organizational knowledge that enables the development of a new or improved product, a new or improved product production process or an inter-related product-process innovation. Specifically, this thesis sets out to investigate the knowledge-creation process within an industry that has excelled in the 'knowledge era'. It is hoped that the findings will prove useful in better understanding how relevant knowledge is created, and, in turn, how corporate R&D in general might be more effectively managed. The research question that forms the point of departure may be stated as: In what way should knowledge be created in corporate R&D? The investigation uses findings from the R&D and Knowledge Management literature. It also uses new

findings from an empirical study into corporate R&D in the UK pharmaceutical industry between the years 2000 and 2003, since there appeared to be a significant consensus at the time that UK pharmaceutical R&D compared favourably with the R&D of other industries.

Despite a widespread acceptance of the 'knowledge economy' within academic circles, it was the present author's experience that the importance of knowledge working had not generally been accepted within R&D circles. In order to understand how knowledge is created within corporate R&D, the research upon which this thesis is based therefore focused on those areas deemed most important in determining how knowledge is created in an R&D context, namely: the strategic approaches, the daily practices, and the knowledge processes employed in corporate R&D. This focus led to four specific aims of the research. These aims are outlined in Section 1.2 of this chapter. The themes that emerged as the work progressed are described in Section 1.3. And, an overview of the remaining chapters of this thesis is provided in Section 1.4.

1.2 The Specific Aims of the Research

The first aim of the research was to identify the approaches and practices employed within corporate R&D, and the possible influences these approaches and practices might have upon the knowledge creation process, in order to provide the background for the empirical study into knowledge creation in corporate pharmaceutical R&D. The R&D Management literature provides descriptions of how R&D functions have been organized over the past decades and the changes that have occurred. This literature is reviewed and the typical approaches and practices are described in Chapter 2 of this thesis.

The organizational changes reported in the R&D Management literature are reflected in the Knowledge Management literature's 'Mode 1-Mode 2 knowledge production' debate instigated in 1994 by Michael Gibbons and his co-workers. Despite these authors' claims that knowledge production within the context of application (Mode 2) would come to predominate over knowledge production within a disciplinary context (Mode 1), there was some doubt in the present author's mind that such would or should be the case. The second aim of the research was to determine the extent to which these two forms of knowledge production are important in contemporary corporate R&D. It was the hope that, by adding to the Mode 1/Mode 2 debate, the research would make sense of and provide a richer interpretation of how organizational knowledge is actually produced. This is not to say that the debate was without value. On the contrary, it provided a useful vocabulary for interpreting changes in the R&D climate. For example, it could be related to the shift in British science policy away from the linear (Mode 1) model where science invented and industry developed, towards the joint development of science for a particular commercial purpose (Mode 2) pioneered by countries such as Japan and Australia. As will

be shown later, it is not, however, the whole story. Gibbons and co-workers' proposals are described in Chapter 3; their importance is discussed in Chapter 6.

Other workers have looked more closely at the actual knowledge creation process. The knowledge conversion cycle of Ikujiro Nonaka and Hirotaka Takeuchi is considered particularly important because of its reference to tacit knowledge (Nonaka and Takeuchi, 1995). It has, however, been criticized because of its very reliance on conversions between four distinctly different forms of knowledge – tacit knowledge and explicit knowledge, of the individual and group varieties – which by definition defy the possibility of conversion. In consequence, Scott Cook and John Seely Brown proposed several shifts that they believed built upon Nonaka and Takeuchi's work and also answered this particular criticism. The result is a pluralist framework which differentiates between different categories of 'knowledge tools'– Nonaka and Takeuchi's four forms of knowledge – that are possessed, which are used in the 'active process of knowing' (Cook and Brown, 1999). Yet, since the earlier work of Michael Polanyi has shown us that all knowledge contains a tacit dimension (Polanyi, 1966), we might question both the categories of 'knowledge tools' proposed by Cook and Brown, and the distinct 'forms of knowledge' suggested by Nonaka and Takeuchi. The third aim of the research was to examine the extent to which these models might be useful in describing knowledge creation within an R&D context. These models are also described in Chapter 3, and discussed in Chapter 6.

Finally, it was hoped that an investigation into the way in which knowledge is created within UK-based pharmaceutical R&D would serve as a basis for the identification of more general insights into the practice of corporate R&D. The practice of corporate R&D is discussed in Chapter 6, Sections 6.5 and 6.6.

1.3 The Themes in the Thesis

One theme that emerged from the empirical study upon which this thesis is based is that the work of R&D is not the work of a single entity but is that of two distinctly different collectives, one associated with research and one associated with development. And, importantly, although these collectives overlap, the approaches, the practices, the knowledge, and the knowledge processes used within and necessary for knowledge creation in research differ significantly from those suitable for and prevailing in development. In essence, these differences may be explained by the fact that research is about the exploration for new knowledge, whilst development is about the exploitation of existing knowledge. It is a suggestion of this thesis that these fundamentally different knowledge purposes impose specific requirements upon how research and development are managed to the extent that, to a degree, research should be the master of the organization whilst the organization should definitely be the master of development.

A second theme that emerged as the research progressed was that, as in much of life, the assumptions made and the perspectives adopted can significantly affect the way in which we view things. This was particularly so in relation to the models of organizational knowledge creation outlined in Chapter 3 of this thesis. For example, if we accept that the terms 'tacit' and 'explicit' refer to two distinctly different forms of knowledge, then we might accept the pluralist framework of Cook and Brown. In so doing, we can show quite clearly the distinctly different knowledge requirements of corporate research and development (Chapter 6, Section 6.4.2). If we cannot accept these two forms of knowledge, a view that would appear to agree with Polanyi's work, then these differences are either meaningless or require significant adjustment.

Finally, it is interesting that many of the participants of the empirical study upon which this thesis is based mentioned 'communication' as being perhaps the one most important factor in ensuring success within R&D. Whilst this finding has no doubt been influenced by the topic of interest and by the way in which this study was conducted, it will be shown later that, despite the distinctly different approaches adopted in pharmaceutical research and pharmaceutical development, knowledge acquisition and knowledge sharing, as defined in the next section of this chapter, are essential requirements of both these activities. Without the opportunities that arise from the instinctive practices that develop between lifetime colleagues within tightly bound organizations such as exist in Japan (Ray *et al,* 2000, p.3), it is hardly surprising that communication is important. The problem is that there is more that needs to be acquired, shared and then applied than the 'knowledge' that is normally associated with the spoken word.

1.4 An Overview of the Chapters

In addition to the present chapter, this thesis contains a further six chapters covering, in turn: a literature survey of the approaches and practices of corporate R&D; a literature survey on knowledge creation; the research methodology; the findings of the empirical research; the discussion of these findings; and a conclusion. The subject matter of these chapters is briefly outlined below.

There has been much written about the management of corporate R&D, yet there have been few reports that have adopted a knowledge perspective.[2] So, although, it has generally been recognized that there is probably 'no one best way' to manage the practices of R&D, Chapter 2 (Corporate R&D: A Literature Review) attempts to make sense of the approaches and practices observed by others in order to outline the general context within which knowledge is being created within this area of corporate activity. Five broadly defined approaches, often referred to as the 'R&D Generations', are described. And, whilst the progress from one approach to the next has been attributed to changes in market forces and advances in technology, this progress would appear to be far from complete and far from being a certainty. At the same time, the daily practice of professional R&D workers would seem to be remarkably consistent; they want to generate the appropriate knowledge. The question of what constitutes 'appropriate' is, however, shown to vary enormously according to the approaches adopted and the particular stage of the R&D process. The chapter highlights the types of knowledge that are appropriate in typical instances.

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[2] Notable exceptions are: Faulkner, 1994: Gibbons *et al*, 1994; Leonard-Barton, 1995; Liyanage *et al*, 1999; Nonaka and Takeuchi, 1995; and Madhavan and Grover, 1998.

Chapter 3 (Knowledge Creation: A Literature Review) begins with a brief discursion into the views of some 20th century philosophers regarding the growth of knowledge in the scientific community at large. It then looks into the complex and inherently personal nature of what is generally referred to by the term 'knowledge', and draws the conclusion that it is information, not knowledge, that can exist independently, and which can thus be directly acquired or shared. Knowledge acquisition and knowledge sharing – or, in general, the flow of knowledge – is dependent upon the providers and receivers of information accepting and understanding the same 'interpretation code' for that information – a far from guaranteed reality. Processes such as knowledge acquisition, knowledge sharing, and knowledge transfer within this thesis are then defined accordingly. The chapter then moves on to review the Mode 1 and Mode 2 approaches to knowledge production defined by Michael Gibbons and his co-workers (1994); the organizational knowledge creation and conversion cycle suggested by Ikujiro Nonaka and Hirotaka Takeuchi (1995); and the pluralist framework of knowledge and knowing described by Scott Cook and John Seely Brown (1999). Finally, the chapter revisits Michael Polanyi's earlier work on the 'tacit dimension' (Polanyi, 1966) to outline how we may each create our own personal knowledge, an acceptance of which has serious implications for the models of Nonaka and Takeuchi and Cook and Brown mentioned above.

Chapter 4 (The Research Methodology) notes the major assumptions made, and makes the case for the use of more explorative techniques to uncover and understand current practices in corporate R&D. In particular, the chapter refers to the still emergent state of theorizing and research into the importance of knowledge-based approaches to firm performance, which render quantitative techniques inappropriate. And, it describes the need for an adaptable but indirect observational technique, which led to the decision to employ a semi-

structured interview method for the collection of empirical data, interviewees being managers responsible for the research and/or development functions of their respective organizations. The chapter describes in detail the procedures employed in selecting the 'more successful' R&D organizations for sampling, the actual interview (data collection) process, and the subsequent manual method of data analysis.

Chapter 5 (The Findings of the Empirical Research) summarizes the findings from the empirical study. In contrast to the earlier literature, much of the more recent management literature appears to have treated the R&D process as if it was a single activity (albeit involving several iterative stages).[3] For most companies in most industries this may be perfectly adequate, since much corporate R&D is perhaps closer to D (development) than R (research). However, the pharmaceutical industry is one industry in which *both* research and development activities are carried out. Perhaps the strength of this present study is that it has, for this reason, been able to highlight the differences between corporate research and corporate development. Specifically the chapter shows how the approaches, the practices, the knowledge, and the fundamental knowledge processes used within and necessary for knowledge creation in research differ significantly from those suitable for and prevailing in development.

Chapter 6 (Discussion) revisits the literature reviewed in Chapters 2 and 3 and discusses its relevance in the light of the findings reported in Chapter 5. First, the positions of pharmaceutical research and pharmaceutical development are pinpointed on the 'R&D Generations' scale: research is related to first generation R&D, and development to third and fourth generation R&D. Second, the importance of both Mode 1 and Mode 2

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[3] More recent exceptions are: Kumpe and Bolwijn (1994) and Becerra-Fernandez and Sabherwal (2001).

knowledge production is determined in relation to pharmaceutical research and pharmaceutical development: research is described as a transdisciplinary Mode 1 type activity, and development as a coordinated Mode 2 type activity. Third, the relevance of each of the three 'models' of organizational knowledge creation is discussed in relation to pharmaceutical research and pharmaceutical development: whilst Nonaka and Takeuchi's model points us towards the types of knowledge processes important for knowledge creation in each of these contexts; and whilst Cook and Brown's model emphasizes the fact that we use the knowledge available to us at the time to pursue our various activities; it is Polanyi's proposal that knowledge creation is the result of purposeful (if sometimes indeterminate) acts of tacit knowing that provides the predictions that accord with the findings of this present study. Fourth, the chapter looks at the different knowledge creation processes in research and in development and makes some suggestions as to 'why things are as they are'. In so doing, it suggests that it is the 'needs of research' that determine how research is managed, but is the 'needs of the organization' that determine how development is managed. The chapter concludes with a review of the various factors deemed to be the most important in achieving success in corporate 'R&D', factors which relate to the need for commercial viability in development, whilst ensuring a degree of exploration in research.

Chapter 7 (Conclusion) summarizes the major conclusions, highlights the major contributions made, and outlines the principal limitations of, and some possible extensions to, the work reported herein.

2 CORPORATE R&D: A LITERATURE REVIEW

2.1 Introduction

From a strategic perspective, corporate R&D might be viewed as 'investment in invention', the generation of new knowledge that, given an appropriate combination of resources and circumstances, could result in an innovation that enhances or redirects the firm's capacity to compete. Yet, the potential costs and benefits of investing in invention are shrouded in uncertainty. Significant resources might be consumed by activities that do not unfold in the way that was initially expected, while the opportunity-cost of pursuing, what are subsequently judged to be, unsuitable R&D trajectories can have serious implications. Yet, knowledge created during apparent failure might also be a stepping-stone to tomorrow's success. Clearly, there is a high premium on generating insightful judgments about R&D policies that take suitable account of evolving patterns of constraints and opportunities. However, there would appear to be considerable disagreement about what constitutes 'best practice' in any given circumstance. Nevertheless, this chapter attempts to make some sense of the approaches and practices described in the R&D Management literature, in order to outline the context within which knowledge is being created in this study. Chapter 3 then uses the Knowledge Management literature to identify specific approaches to the production or creation of knowledge.

Building on the benefit of hindsight, five broadly defined basic approaches to R&D have been recognized or advocated in the literature. Often referred to as the 'R&D Generations', these different approaches have, in the main, been attributed to changes in

market forces and advances in technology, particularly information and communications technologies (ICTs), which have required or enabled companies to alter their strategic stances and adopt different organizational forms and management procedures (Kumpe and Bolwijn, 1994; Varma, 1995; Rogers, 1996; Ahmed, 1998; Liyanage *et al*, 1999). Certainly, the present author's personal experience, generated during two decades as an R&D practitioner, supports the view that different organizations have adopted these approaches to varying degrees, and, indeed, that influences associated with several or all of these approaches may be evident in the same organization at the same time (Pearson, 1991, p.21). The advent of a new generation does not necessarily erase the legacy of what went before and the progression from first to fifth generation approaches is not necessarily unidirectional in sequence. As Rothwell and Zegveld point out, 'the linkages between science, technology and the market place are complex, iterative and multidirectional' and 'within particular branches of industry causality can switch from being mainly in one direction to being mainly in the other' (Rothwell and Zegveld, 1985, p.65).

At the same time, the daily practice of professional R&D workers is in many ways remarkably consistent: they want to generate appropriate knowledge. Thereafter, the picture becomes more complicated: the question of what constitutes 'appropriate' can vary enormously according to the perspective and interests of the observer. R&D is only one part of the firm's activities, and the extent to which different people feel that it should lead, or be guided by, corporate strategy is shaped by personal perspective and prevailing circumstances: it depends on whom you ask within the firm and the nature of the firm's business. As the empirical work presented in Chapter 5 will illustrate, corporate R&D simultaneously shapes the generation of knowledge and is shaped by a shifting constellation of influences which operate across the firm and its wider environment.

Briefly, the five generations of R&D covered in Section 2.2 of this chapter comprise: science/technology-push; market-pull; integration of activities within the firm; external collaborative working with wider communities; and virtual networking. Although the latter three generations might be associated directly with recent Knowledge Management and related discourses, a knowledge-based approach can also be used to deconstruct the more historical science/technology-push and market-pull debates. Indeed, as the next chapter will suggest, the science/technology-push model may be seen as the precursor to what Gibbons and his colleagues have called Mode 1 knowledge production, whilst the later R&D generations increasingly embody practices that fall within the general scope of what these authors refer to as Mode 2 knowledge production (Gibbons and Johnston, 1974; Gibbons *et al*, 1994; Gibbons, 2001; Gibbons, 2003; Nowotny *et al*, 2001; Nowotny *et al*, 2003).

Although successive generations of corporate R&D have moved the focus of management attention from exogenous knowledge generation to endogenous invention and then back to the exogenous influences associated with wider networks and cyberspace, paying undue attention to either the macro or micro level is simplistic and can be misleading: the innovating firm plays a vital role in brokering complex connections between the detail of corporate R&D and the bigger picture. Accordingly, Section 2.3 looks at the practice of R&D, specifically at the R&D process.

Section 2.4 summarizes the main points of the chapter.

2.2 R&D Approaches

Arguably, the first and second R&D generations are essentially two sides of the same coin, which is a point that is recognized in the third R&D generation where the emphasis on science/technology-push that characterized the first generation was complemented by attention to market-pull influences that framed second generation approaches. These early models placed the focus of attention on intra-firm activities. However, no firm can ignore the context in which it operates. Subsequent R&D generations embraced exogenous influences on the nature of the firm's daily business and direction of corporate strategy.

2.2.1 First Generation R&D: Science/Technology-Push

Many of the great technological innovations associated with the birth of the industrial era were undoubtedly based on the entrepreneurial exploitation of practical insights and learning that took place in the course of seeking more rapid (Hobsbawm, 1968, p.34) and more advantageous ways of doing things (ibid, p.43). Spurred on by the growth and acceleration of overseas trade (ibid, p.34), the process of competitive innovation which propelled Britain into the industrial era and paved the way for many of the great engineering achievements of the Victorian period typically owed more to practical experience and know-how (ibid, p.44) than to the formal learning associated with embryonic university disciplines (ibid, p.45) – which was to become the foundation of Mode 1 knowledge production. Rather than science paving the way for technology, it would appear that it was technology that led to further technology (de Solla Price, 1975, p.50). And, academic science generally took more from industry than it could offer in

return. Nevertheless, whilst formal scientific training was often absent, it has been suggested that informal scientific learning through personal efforts and contacts played a part in these major advances of the nineteenth century (Jewkes *et al*, 1958, p.66; Hobsbawm, 1968, p.43). By the end of the nineteenth century, progress in physics and chemistry had, however, started to inform the development of new trajectories of technological innovation, notably in the US electrical and the German chemical industries (Hobsbawm, 1968, p.146; Graham, 1985, p.49; Rothwell and Zegveld, 1985, p.32). Science had reached the point where it could offer discoveries that had commercial implications, some of which were coupled to user needs by insightful entrepreneurs (Schumpeter, 1912, in Hobsbawm, 1968, p.145; in Rothwell and Zegveld, 1985, p.28; and in Utterback, 1994, p.192).

By the early 1900s, a number of R&D laboratories had been established within some of the larger Western organizations in order to exploit the opportunities that science offered. Initially, the focus of attention was directed towards the processes by which things were made, but later the focus turned to the internal development of production products. Instead of merely scanning the external environment for inventions in which to invest (exogenous invention), corporations started to invest in the production of invention (endogenous invention), and, in science-related industries, the R&D department became established as an important internal source of innovation (Varma, 1995, p.232).

The view that *science-discovered* and *technology-applied* became an embedded part of government policy for science in countries such as the US and UK. Science seems to have played a major role in the period after the Second World War, with science-related technologies – nuclear weapons, nuclear power, rockets, radar, thermoplastics, jet engines,

and so on – achieving a high profile. The policy lesson seemed to be simple: invest in publicly funded basic research and economic growth would take care of itself (Rothwell and Zegveld, 1985, p.50) – although the 'miracle' growth of economies such as Japan, which spent a comparatively low proportion of GDP on basic research, eventually prompted some fresh thinking.

Up to the 1960s, corporate laboratories tended to operate in isolation from the rest of the organization. They often occupied sites that were separate from the main business functions: a semi-autonomous 'Ivory Tower' that was protected by the corporate umbrella. In line with US and UK government policies, the assumption was that economic gain would inevitably flow from the work undertaken. There was an emphasis on long-term research, with scientists generating projects on the basis of a company's portfolio of research interests:

> 'Corporate R&D was assumed to be a valuable and cost effective investment for the company's growth … Industrial scientists saw their primary objective as being one of discovering and inventing, albeit within a corporate context. Many technical managers supported basic and long-term research of science, without much regard to development. They believed that the cumulative benefits of research would automatically produce products and processes of great value to the company.' (Varma, 1995, p.235)

R&D was managed as part of a traditional, hierarchical, functionally driven organization (Rogers, 1996, p.36). The R&D 'team' consisted of an individual or a small group of scientists, who knew each other well, who all 'spoke the same language', and who were led by a technical 'manager'. Great emphasis was placed on individual creativity and the undertaking of scientific discovery with minimal bureaucratic controls (Burns and Stalker, 1961, p.159) and there were few formal techniques for the selection and evaluation of projects.

The discovery-push approach to corporate R&D knowledge creation was thus functionally split, with the various activities – research, development, production, marketing – taking place serially (Rothwell, 1992, p.236). This 'stage-gate' process was likened to a 'relay race' where the process 'baton' passes from one team to another as each stage is completed and the next begins, although as most authors emphasize there may be many iterations and feedback loops between the various stages before completion (Rothwell and Zegveld, 1985, p.48; Kumpe and Bolwijn, 1994, p.38). As the principal supplier in a 'sellers' market for new ideas, research could 'take its time' in creating, analysing and perfecting scientific knowledge, whereas development concentrated on reducing costs (Kumpe and Bolwijn, 1994, p.38). However, this task-separation meant that R&D workers had little appreciation of the overall business activities of the organization and business functions similarly had little understanding of the problems that were endemic to R&D.

2.2.2 Second Generation R&D: Market Pull

By the 1960s, it became apparent that simply waiting for the R&D department to come up with an invention that was ripe for innovation was not necessarily a recipe for commercial success (Kumpe and Bolwijn, 1994, p.3). Although competition from countries such as Japan was initially dismissed as being limited to low-technology, low-quality and often unreliable products, continuous improvement innovations by Japanese manufacturers progressively paved the way to new standards for high-technology, high-performance products that redefined global expectations about reliability. Despite spending a comparatively low proportion of GDP on basic research, Japanese producers improved

market share and conquered new markets by aligning their trajectories of improvement innovations with the evolution of market needs.

Meanwhile, it was recognized that although many Western corporate laboratories had produced promising research results, these results were not always translated into viable products or production processes (Varma, 1995, p.235). Perhaps in an attempt to emulate their Japanese counterparts, Western organizations focused their efforts on customers' needs (Rothwell and Zegveld, 1985, p.49). The process of R&D adopted a reactive role (Rothwell, 1992, p.236). Cooperation between R&D and marketing and between R&D and manufacturing increased, and many companies established local technical units to support local sales and marketing operations (Kumpe and Bolwijn, 1994, p.40). The knowledge creation process remained essentially linear (Ahmed, 1998, p.47), but close attention was now paid to design aspects such as 'producibility and serviceability' (Kumpe and Bolwijn, 1994, p.40), and projects were selected on the basis that they would deliver tangible results within a specified time period (Liyanage *et al*, 1999, p.376). Although scientific and technical knowledge creation remained largely the province of the central R&D department, marketing, design, and operations knowledge became important inputs into the process (Kumpe and Bolwijn, 1994, p.40).

By the end of the 1970s, a wide array of new technologies had led to the introduction of a diverse variety of products and processes into many markets. Local technical units were also increasingly developing additional products to meet their particular local requirements. As a consequence, companies began to experience difficulties in developing and supporting an ever-widening product range (Kumpe and Bolwijn, 1994, p.40). There was an increasing emphasis on process improvements (Rothwell and Zegveld, 1985, p.33)

in order to compress development times (Rothwell and Zegweld, 1985, p.51). These improvements included concurrent engineering, simplification of designs, optimal use of proven technologies, standardization of components, the use of CAD-CAM technologies, and the outsourcing of some non-strategic technologies (Kumpe and Bolwijn, 1994, p.41). Products were designed with the objective of being produced efficiently and effectively using existing manufacturing capabilities (ibid, p.41).

By the middle of the 1980s, the centralized corporate R&D laboratories of many international companies had been physically restructured around their various business units (Varma, 1995, p.232), and the availability of business money directed research:

> 'Now, managers and scientists have to work with one of the business divisions to encourage joint projects between scientists and business divisions' people. The cooperation between research and business divisions is enforced by changing the funding scheme. Scientists have to obtain contracts from business divisions for their research efforts.' (Varma, 1995, p.236)

Yet, these new power structures could be a source of tension: business divisions with their need to maintain short-term profit for shareholder return were not necessarily geared towards long-term scientific research, even if ultimately that research could bring them considerable competitive advantage. There were consequently problems in gaining funds for science/technology led projects. Business divisions were not willing to take the risks involved and were perhaps not, singly, able to provide the larger sums of money required. The power to select promising projects had moved from those favouring an emphasis on technical viability towards those whose principal concern was with commercial viability. Rather than rewarding scientific excellence, the model encouraged scientists to generate research and development (typically with an increased emphasis on development) towards the solution of specific problems of the business divisions.

Specific problem solving broadened the knowledge horizons of individual R&D (and other) workers, but meant that there was little focus to the functional knowledge created. The result was that exploitation of existing knowledge often prevailed at the expense of basic scientific knowledge creation. And, with the new focus on specific market needs, certain parts of the broad spectrum of technical opportunities were sometimes overlooked (Weick, 1979, p.69). As recognized by Varma, this blurred the goals of R&D:

> 'Under the autonomous [first generation R&D] model, goals for R&D were well established. Managers clearly stated what business the company was in; what business the company was going to be in ... scientists were able to link their research agendas to the broad goals and objectives of the company ... Since the mid-1980s, goals for corporate R&D have become rather vague ... corporate leaders are supporting corporate R&D as a discretionary item rather than providing a steady support ... Managers are ... directing research to solve specific problems. Both scientists and managers reported that their companies did not have plans for what their products would be in 3-4 years, or what businesses they would be in 5-10 years later' (Varma, 1995, p.240).

To the extent that the R&D and managerial interests represented had evolved independently, communication between the different interest groups could be awkward; neither side quite spoke the other's language – and there were often diverging expectations about what constituted 'best practice' and 'progress'.

2.2.3 Third Generation R&D: Business Integration

Third generation R&D arose from a need to consolidate the link between R&D and business strategies, particularly marketing strategy (Roussel *et al*, 1991, p.2; Rothwell, 1992, p.236). Research planning became a corporate function and specific R&D programmes were formulated jointly between business and R&D managers so that both technical and market needs and strengths could be adequately engaged. Projects were

treated as a group of important investment portfolios that should be managed like any other production input such as labour or capital (Kumpe and Bolwijn, 1994, p.41; Rogers, 1996, p.36) and quantitative methods were employed to ascertain the likely contribution of individual projects.

Project managers were put in charge of significant programs and multifunctional matrix coordinated R&D teams became common (Liyanage *et al*, 1999, p.376). Scientists and technologists became more intimately aware of business needs, and the business division people became familiar with the scientific and technical expertise available to them. There was increased intermingling across the boundaries of previously separate spheres of responsibility as technical, production and business staff worked and learnt together as part of an 'ongoing social process in which problems were solved and new problems were identified (Best, 1990, p.12; Rothwell, 1992, p.236). In essence, knowledge creation became transdisciplinary (see Gibbons *et al*, Chapter 3, Section 3.4.1, page 103).

During the late 1980s and early 1990s, it was thought that geographic proximity to external researchers might be conducive to successful R&D, since 'technological spillovers' could occur (Crane, 1972, p.63; Kuemmerle, 1998, p.113; Gassmann and von Zedtwitz, 1999, p.241; Meyer-Krahmer and Reger, 1999, p.757). Companies therefore began to locate some of their R&D units close to relevant centres of scientific excellence. However, the possible benefits of networking across organizational boundaries had to be offset against the costs of relocation. Since the mid 1990s, many companies have therefore rationalized their R&D units by locating them either (a) close to large markets (demand led units) to provide local and regional development and technical support, and exploit existing knowledge in an incremental way; and/or (b) close to external centres of excellence

(supply led units) in an attempt to gain expert knowledge, and create radically different products and processes (Chiesa, 1996, p.12).

Arguably, third generation R&D exhibits the problems of trying to reconcile factors that stretch far beyond the firm with a view of the organization as a self-contained entity. The idea that business integration is merely a matter of identifying and consolidating market and technical needs and trying to ensure that employees march in-step towards meeting those needs overlooks the fact that the firm is part of the wider knowledge-creating ecology and that its capacity to exploit boundary-spanning interconnections can play a vital role in the pursuit of competitive advantage. Subsequent R&D generations have acknowledged this and allow scope for modification through formal and informal collaboration.

2.2.4 Fourth Generation R&D: External Collaboration

Traditionally, corporate R&D was carried out in-house, the expectation being that the organization would hold or create all of the knowledge that it needed to carry out its particular pursuits. However, more recently, there has been a major shift to acquiring technology from sources external to the firm (Freeman, 1992, p.95; Quintas and Brauner, 1999, p.49; Roberts, 2001, p.31). Many organizations now engage in technology in-licensing (and out-licensing); outsource some (and in some cases all) of their R&D to others; participate in research collaborations or joint ventures; and are involved in knowledge networking activities with universities, customers, suppliers, companies in related fields, and even, on occasions, with direct competitors (Freeman, 1992, p.99;

Rothwell, 1992, p.236). Four factors are frequently mentioned in the literature as being important in motivating the change towards external R&D collaboration.

First, R&D has become an increasingly complex and expensive exercise for all organizations. This is because (i) the necessary scientific and technological knowledge has become increasingly differentiated and specialized (de Solla Price, 1975, p.139), and (ii) increasingly knowledgeable customers have expected more from new products and services (Kumpe and Bolwijn, 1994, p.44). The result is that several scientific or technological knowledge sources are now often required to produce the most acceptable goods and services, increasing the costs of R&D (Leonard-Barton, 1992, p.33; Powell *et al*, 1996, p.118; Bowonder and Miyake, 1999, p.85; Kodama, 1999, p.186; Niosi, 1999, p.110; Roberts, 2001, p.30). Increasing R&D costs have, in turn, led companies to rationalize their areas of scientific expertise around their core competencies, the assumption being that, when necessary, they could 'buy-in' the latest technologies required to support these competencies (Powell *et al*, 1996, p.118; Niosi, 1999, p.110; Pyka, 2000, p.28).

Second, R&D is an uncertain business, and costs arise whether or not events unfold in an advantageous manner. Collaborating with other organizations is one way of reducing the firm's exposure to the costs of undesirable events. It reduces the stake by spreading the costs between participants and thus effectively reduces any losses that might occur, albeit at the cost of sharing the outcomes with others (Powell *et al*, 1996, p.116; Niosi, 1999, p.110; Beeby and Booth, 2000, p.76). Collaboration with companies in related fields that are not direct competitors, and that are not likely to become so, offers scope for each party to gain without eroding their respective positions. For example, collaboration between a

supplier and a customer is often of mutual benefit to both parties: the customer benefits from the additional ideas advanced by the supplier; the supplier benefits from understanding and better providing for the customer needs (Best, 1990, p.15).

Third, by applying the skills of more than one organization, collaborative problem solving may reduce the time to market and thus increase the producing organization's lead over its competitors; a state that may be particularly important at a time of rapid technological change (ibid, p.15).

Fourth, a common interest can be a powerful motivator for collaboration (ibid, p.18). Consider, for example, the use of PVC (polyvinyl chloride) in window frames and other applications involving direct human contact. In the 1990s, PVC was considered to be a health hazard: it contains trace amounts of vinyl chloride monomer (a carcinogen). Environmental groups lobbied for a total ban on the use of PVC. Collaborative research by the PVC suppliers and users showed that, once processed, not only was PVC as safe as the then commercially available alternatives, but also that it was more environmentally friendly in that PVC products can be recycled whilst many of the alternatives of the time could not.

Along with the four traditional motivations for collaboration, the Knowledge Management literature has underscored the importance of 'path dependency'. Path dependency arises because existing knowledge often determines the way that new knowledge is interpreted and the way that existing and new knowledge is applied (Brook, 1973, p.30; Weick, 1979, p.46). The argument is that as well as bringing in new knowledge, collaboration also decreases the path dependency by bringing in new perspectives based upon the

collaborating partners' different knowledge sets. This increases the chance of creating something uniquely different to what might have been possible by in-house development alone (Bowonder and Miyake, 1999, p.85). That is, collaboration increases the chance of radical innovation.

In Kumpe and Bolwijn's interpretation of fourth generation R&D, external collaboration is seen as just one organizational form that companies adopt in order to compete on the basis of 'uniqueness' (product differentiation) as well as price, quality and performance (Kumpe and Bolwijn, 1994, p.42). Writing in 1994, these authors suggested that, within the company, various organizational forms would coexist alongside one another depending upon the requirements of the specific activities being undertaken. There would be considerable use of multidisciplinary *ad hoc* teams, and integrating managers would direct and coordinate the various activities from research to production and from components to products. They predicted that organizations would need to strike the right balance between 'renewal and stability' and between 'entrepreneurship and the tight, hands-on management of innovation'. In their view, external collaborations offered the flexibility of working with ideas new to the firm, and at the same time allowed a degree of stability as regards internal technology development (ibid, p.43).

The importance of customers as sources of knowledge, ideas, and expertise in the R&D process has been emphasized by several authors (see for example, Langrish *et al,* 1972, p.74; von Hippel, 1976, p.212; Best, 1990, p.15). And, both Miller and Rogers saw fourth generation R&D as the process of concurrent learning with these customers (Miller, 1995, p.30; Rogers, 1996, p.37). In particular, collaborating with customers in cross-functional, cross-disciplinary teams was said to be essential for understanding future business

opportunities, and thus for the development of valuable new products and services (Miller, 1995, p.31). Ahmed noted that it might also be advantageous to involve suppliers in the process (Ahmed, 1998, p.48). However, Teresko's research questions whether such relationships are sufficient for continued success in R&D:

> 'A [US] presidential advisory committee questions whether [customer-supplier collaborations are] enough to seed the growth of technology-based business over the next 10 to 15 years ... [It] points to the economic and social benefits that have come from federal funding of research into computers and telecommunications.' (Teresko, 1999, p.30)

Liyanage *et al* come to a similar conclusion and suggest that fourth generation R&D is not simply about the management of customer or supplier linkages, but about the management and integration of the appropriate external knowledge with the internal knowledge of the organization. In particular, it is about renewing outdated concepts with current or 'state-of-the-art' knowledge acquired through rational enquiry and observation from whatever source (Liyanage *et al*, 1999, p.373).

2.2.5 Fifth Generation R&D: Virtual Learning Networks

Several management researchers have remarked that economic, behavioural and technological forces are prompting organizations to explore virtual networked structures that transcend conventional organizational boundaries. Such structures have been defined as opportunistic alliances of core competencies distributed among a number of distinct operating entities within a single large company or group of companies (Goldman *et al*, 1994, in Rogers, 1996, p.39). They offer the possibility of combining expertise from a range of sources both within the firm and across its wider operating environment.

Rothwell (1992), Rogers (1996) and Ahmed (1998) appear to be the most prominent in charting the dimensions of fifth generation issues.

Rothwell suggests a systems integration and networking (SIN) approach based upon the third generation business integration and fourth generation collaborative approaches outlined above, but specifically involving strong linkages with leading-edge customers and strategic integration with primary suppliers. The emphasis is on corporate flexibility, speed of development, and quality, through the 'electronification of innovation'. That is, expert systems, such as simulated modelling of prototypes and integrated electronic design/ manufacturing systems, are employed within a multi-institutional networking environment in which conceptualization leads practice (Rothwell, 1992, p.237).

Rogers identifies five major shifts that are driving the move towards such organizations. These shifts comprise moves from: tangible assets (information) to intangible intellectual assets (knowledge) as the sources of wealth that need to be managed; formal bureaucracies to networks that afford the flexibility needed to harness the maximum potential of available intellectual capabilities; passive training and development with a focus on the trainer and the curriculum to active learning that places the learner at the heart of the activity; a focus on the local or national level to transnational foci; and competitive (win-lose) strategies to collaborative (symbiotic) strategies that allow more wealth creation than would be possible by operating alone. She proposes that the way in which organizations use their human resources to optimize their organizational learning capacity will be crucial in enabling a more optimal creation and application of new knowledge (Rogers, 1996, p.33). Importantly, she suggests that all participants in the virtual network must be willing and able to continuously learn from each other to create new knowledge as a way of adding

value to the entire system. She offers several predictions, namely: that performance will be assessed in terms of the intellectual assets produced and the capacity to create and apply new ideas in the market place; management practices will be fluid and flexible and will be knowledge-based; management systems will be collaborative, not competitive or cooperative; and internal R&D, as just one part of the collaborative learning system, will focus on designing its innovation system in collaboration with its network affiliates. As a consequence, she suggests that knowledge flows will need to be optimized throughout the network and managers will need to monitor knowledge flow rigorously with an attention to detail that reflects the way in which they previously managed the monetary flow of capital and the flow of parts and materials into products and services (Rogers, 1996, p.37).

Rogers' report suggests that the exploitation of external knowledge and skills first becomes important through outsourcing and licensing agreements. Later, and more importantly, transorganizational knowledge is created as people from different organizations work together to create new products and processes; in so doing, they contribute to the overall progress in science and technology by 'bidding-up' the currency of 'best practice'. Such joint working is not necessarily restricted to collaboration between a university and an industrial concern but might involve a number of organizational entities such as commercial research institutes, organizations in related industries, and even organizations that would normally be thought of as competitors. Although the knowledge created by such collaborations may be exploited differently, it is available to everyone who participates - participation being essential to make sense of the outputs. Formal and informal knowledge sharing networks abound, leading to a complexity of interactions – scientific, technical and business – within and without the organization (ibid, p.37).

In agreement with Rothwell, Ahmed sees fifth generation R&D emerging as a consequence of the increased utilization of electronic technology as a tool for facilitating the creation of a variety of internal and external linkages. However, in contrast to Rothwell's more managed approach (page 30 above), Ahmed implies a more informal arrangement. Linkages that are mutually beneficial to participating parties tend to become self-sustaining: people perceive that the time and effort needed to take part is of net-positive-benefit. Ahmed suggests that there are a number of factors that are important for successful fifth generation R&D. These include a focus on innovation and discovery; a culture of 'equals'; effective sharing and processing of ideas; process distinctions between radical long-term innovation and incremental short-term business; and keeping and building knowledge, particularly embedded skills and memory. That is, 'soft' issues, such as creating a climate for innovation, are just as important as if not more important than 'hard' issues, such as organizational procedures and infrastructure, to successful R&D (Ahmed, 1998, p.50). Referring to Cooper and Kleinschmidt (1987) and Zirger and Maidique (1990), Ahmed adds that it is in the 'balance between the hard and soft factors that innovation success appears to be founded' (Ahmed, 1998, p.57).

In summary, it would appear that the distinguishing features of fifth generation R&D turn on the capacity of the innovating firm to exploit technological opportunities for working across boundaries. Advances in transport and communication technologies have made it increasingly easy to take advantage of expertise from a diversity of sources. Global virtual teams, which were almost unheard of a decade or so ago, have become an established part of business life. Modern communications technologies make it relatively easy to work across time zones and ensure that the sun never sets on current activity. Virtual networking has complemented the fourth generation notion of face-to-face collaborative

working. As a result, experts are now more aware of the wider communities of practice that are relevant to their respective areas of expertise, thereby providing their employers with greater opportunities to learn, albeit at the risk of allowing outsiders to acquire sensitive information and learn at the organization's expense (Mansfield, 1985, p.222). Alternatively, it is possible that employees with specialist skills will become better able to position themselves as 'free agents' who are able to eclipse traditional bureaucratic constraints by shaping their own work practices and networks of connections and, in so doing, promote their own economic or political agendas (Hayes and Walsham, 2000, p.72).

2.2.6 The R&D Generations: Some Trends Summarized

The previous sections of this chapter have hinted at how the types of knowledge and the knowledge processes employed within corporate R&D vary between the R&D generations. These variations are summarized in Table 2.2.1 (next page).

Broadly speaking, it would seem that two prominent overarching forces have driven the strategic approaches to corporate R&D, and, in turn, the types of knowledge employed in this activity. First, the influence of market forces, which began with the onset of second generation R&D in the 1960s, has elevated the importance of commercial knowledge to corporate R&D operations. Second, this more commercial approach has been complemented by an increasing recognition of the idea that sources outside the firm might provide the key to more effective R&D. This latter force became particularly evident with the rise of fourth generation R&D in the early 1990s.

TABLE 2.2.1: THE R&D GENERATIONS: KNOWLEDGE TYPES AND KNOWLEDGE PROCESSES

Generation	Knowledge Types	Knowledge Processes
Prior to 1900	Product and process knowledge and skills	Scientific and technical knowledge acquisition and internal application.
First Generation: Science/ Technology Push (1900-60)	Basic scientific and technical knowledge.	Internal scientific and technical knowledge creation mainly through exploration and experimentation. Informal Community of Practice[4] knowledge acquisition and sharing.
Second Generation: Market Pull (1960-early 1980s)	Product and process knowledge. Design skills. Business (particularly marketing) knowledge.	Internal knowledge creation mainly through exploitation and adaptation. Formal and informal knowledge sharing between R&D and commercial units (particularly marketing, production, manufacturing).
Third Generation: Business Integration (mid 1980s-early 1990s)	Scientific, technical and commercial knowledge and skills. Project planning and evaluation skills.	Fundamental scientific and technical knowledge creation through exploration by supply-led units. Commercial knowledge creation by knowledge application and adaptation by demand-led units. Formal and informal knowledge sharing between R&D, business, and technical support units.
Fourth Generation: External Collaboration	Basic and applied scientific, technical, and commercial knowledge.	Knowledge creation mainly through knowledge application and adaptation. Internal and external knowledge sharing through formal collaboration and informal knowledge networking. 'Management' of internal and external knowledge and skills.
Fifth Generation: Virtual Learning Systems	Basic and applied scientific, technical, and commercial knowledge.	Knowledge creation, sharing, processing and exploitation through 'opportunism' and as part of a collaborative learning system.

[4] Community of Practice: A group of people who have worked together over a period of time and through extensive communication have developed a common sense of purpose and a desire to share work-related [or specialty] knowledge and experience. They set their own goals, membership boundaries, personal relationships, generalized reciprocity, and production and collection of goods (Sharp, 1997, www, in Quintas *et al*, 1999, p.46).

At the operational level, it becomes difficult to deconstruct the respective influences of the overarching forces identified above. Micro-level corporate R&D processes are complex. Nevertheless, two trends seem evident. First, formal processes of knowledge sharing through collaborative working have been added to and intertwined with the informal processes such as personal networking that have always existed. Second, the importance of sustaining radical new avenues of knowledge creation through exploration and experimentation oriented towards scientific breakthroughs (first generation R&D) has been, largely, replaced by an emphasis on knowledge creation through the application and adaptation of existing knowledge (second to fifth generation R&D). Discovery has become increasing overshadowed by recipes and strategies for producing more effective combinations of existing knowledge. At the same time, different types of people have come to shape the evolution of corporate R&D. Whereas the process of shaping R&D strategy was once dominated by individuals or teams of scientists and technologists (first and second generation R&D), it has more recently been influenced by multidisciplinary and transdisciplinary perspectives, reflecting a wide variety of specialist skills within and outside the organization (third, fourth and fifth generation R&D).

Yet, although each successive generation reflects a shift in the principal focus of attention, it would appear that the influence of earlier generations can still represent an important part of the picture (Pearson, 1991, p.21; Boghani *et al*, 1999, p.696; Gassmann and von Zedtwitz, 1999, p.231. Complex organizations create knowledge in a variety of ways and there are inevitably competing views about what counts as the perspective that matters. Technical experts, R&D leaders and others who enjoyed particular influence during earlier generations of R&D do not necessarily adopt new 'mental models' simply because a new generation of strategic thinking has become popular in the management and business

literature. Similarly, those who are schooled in the market-rational disciplines associated with need-pull models are not necessarily equipped to appreciate the technical risks and opportunities associated with networking in the fourth and fifth generation approaches. Many different 'nested' and 'overlapping' interest groups might jostle to exert their respective influence over the evolution of corporate R&D strategy.

Whilst the differing market and technological factors that exist between industries and indeed between companies within the same industry may thus explain some of the variations observed in corporate R&D strategy (see, for example, the work of Maidique and Patch, 1978, and Abernathy and Clark, 1985), these business level generalizations mask the complexities of micro-level R&D processes. As the issues addressed in the empirical part of this thesis focus on the micro-level, it is important to be clear about the types of issues that might be involved. With this objective in mind, the discussion now turns to the practice of R&D at the level of the innovating firm. The conceptual framework presented in Chapter 6 will draw on principal points arising from this discussion.

2.3 R&D Practice: The R&D Process

The proceeding section has suggested that R&D might be organized in a number of ways: from individualist-centred autonomous units far removed from the other parts of the organization (first and second generation R&D) to cross-functional, cross-organizational, and even virtual team-based units (respectively, third, fourth and fifth generation R&D). At the same time, using corporate R&D as a proxy for corporate innovation, the management of innovation has been viewed as being anything between systematic to chaotic. For example, Drucker proposed that innovation could be systematically managed if one knows where and how to look (Drucker, 1985, p.67). And, based upon his findings that most innovations result from a conscious, purposeful search for opportunities, he proposed several guiding principles: be context relevant – meet user expectations, values and needs; be simple and be focused; start small; aim to be the standard setter; and, most importantly, innovation is hard purposeful work rather than genius (ibid, p.72). On the other hand, Quinn sees the management of innovation as 'managed chaos':

> 'Top managements … tend to administer primarily by helping establish goals, selecting key people, and defining certain critical limits or decision points at which they will intervene. As technology leads or market needs emerge, they set a few - most crucial - performance targets or concept limits …These management then allow their technical units to decide how to achieve these [goals], subject to defined constraints and program reviews at crucial junctures.' (Quinn, 1985, p.275)

The definitive answer to how R&D should best be managed is perhaps still open to debate. Indeed, there probably is no one best way (Walker, 1994, p.6). Nevertheless, it would seem evident that corporate innovation is assisted by individual empowerment, and organizational flexibility, combined with an integrative approach which focuses on the future rather than the past. For example, Kanter writes of the importance of the

empowerment of people; the need to see problems integratively 'as wholes, related to larger wholes'; and of focusing on what is not yet known rather than controlling what is already known (Kanter, 1983, p.27). She suggests that such approaches are more likely in organizations whose cultures and structures are also integrative; that is organizations which whilst allowing multiple perspective approaches also provide overall coherence and guidance (ibid, p.28). She, furthermore, suggests that, in such organizations, experimentation is encouraged (ibid, p.30); the search for solutions is broadened beyond departmental boundaries (ibid, p.29); and specialist biases and political conflicts are resolved through a shared philosophy (ibid, p.32) and pride in the organization (ibid, p.34). Leonard-Barton similarly sees experimentation and integrated problem-solving across different cognitive and functional boundaries as key activities that enable organizations to innovate continuously and consistently (Leonard-Barton, 1995, p.xiv). To these she adds two further activities: importing know-how from outside the organization, and effective implementation of new methodologies and process tools (ibid, p.xv). She also sees innovative organizations as organic learning systems (ibid, p.7) which emphasize long-term thinking (ibid, p.265), and which depend on the sense of ownership derived from suitable incentive systems and the pride of accomplishments gained from shared problem-solving (ibid, p.16). In essence, Kanter's and Leonard-Barton's reports agree with Burns and Stalker's findings that the uncertainty associated with innovation is best enabled by flat, interactive, consultative, organic organizational forms (Burns and Stalker, 1961, p.121) operating from a basis of shared values and beliefs (ibid, p.119), where the power to make decisions is given to those with the relevant ability and expertise (ibid, p.122); rather than hierarchical, bureaucratic, rule-based, mechanistic structures (ibid, p.120), where decisions are made by those holding the power associated with position and specialist function (ibid, p.104).

Empowering individuals might seem to fit with the suggestion normally attributed to Francis Bacon (1561-1626) that 'knowledge is power' (Mintzberg, 1979, p.351). And if knowledge is power, then the owners of knowledge have power that may dissipate if others come to know what they know (Chumer *et al,* 2000, p.xviii). We might then question how empowered organizations do in fact function, since they undoubtedly rely on the sharing of knowledge between their employees. Burns and Stalker offer us an explanation by suggesting that commitment to the organization is far more extensive in organic than mechanistic systems, a fact that is perhaps due to the development of shared beliefs about the values and goals that are to be achieved (Burns and Stalker, 1961, p.122). Whilst this is no doubt true, the present author prefers the view that 'knowledge is potential'[5]. As such, knowledge is there to be used for the good of all. As we shall see in Chapter 5 below (Section 5.4.1, page 176), this would also seem to be the view adopted by the participants of this current study, at least as regards their research activities. The problem, of course, arises when one's contribution to the organization goes unrecognized or, worse, is usurped by others for personal gain.

Most organizations, whether they are innovative or not, will need to carry out a range of routine operations, for example, billing and fulfilling customers' orders, carrying out financial and other audits. For such stable operations, mechanistic approaches offer greater efficiencies (Burns and Stalker, 1961, p.119). Most organizations might therefore be expected to, and in fact do, operate with a management system which includes both organic and mechanistic forms (ibid, p.122). At the same time, organizations are formed

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[5] An alternative translation to the normally stated quotation from Francis Bacon's *Meditationes Sacrae* (1597) is that 'knowledge is itself potential' rather than 'knowledge is itself power.' (Conversation with John de la Mothe, March 3, 2006)

by and with people. And people are social and political creatures. As we shall see in the pages that follow, individual politics and group power *may* each play a part in the decisions that are made concerning products, processes, enabling technologies, and, although related to but not strictly the subject of this thesis, organizational change. As we saw above (Section, 2.2.4, page 27), when people or groups feel threatened, they may take action to reduce or remove that threat. Within organizations, such actions are ostensibly pursued (and mostly believed to be pursued) in the interests of efficiency or as contributions to the firm's tasks and its future prosperity (Burns and Stalker, 1961, p.145). With these thoughts in mind, it is now possible to turn to the specific activities involved in the R&D process, the focus of this section.

There is a burgeoning literature on R&D processes. However, as Tang (1998) has suggested, the practice of R&D would appear to include some or all of the following activities:

1. Scanning the environment for opportunities to be exploited or problems to be solved
2. Generating ideas to satisfy those opportunities or problems
3. Strategically screening ideas to select those meeting corporate goals and fitting with internally or externally available technical and market competences
4. Preliminary investigation or concept testing to determine technical viability and to develop technical and marketing specifications
5. Product development to meet as far as possible the specified requirements
6. Product testing to determine the final product specification
7. Test marketing to determine the appropriate market and entry method
8. Product launch

(Source: Tang, 1998, p.298)

Whilst it is tempting to relate Tang's activities to the traditional stages in the innovation process – invention[6] (Activities 1-4), followed by innovation[7] (Activities 1-5), followed by widespread use (Myers and Marquis, 1969, p.4; Utterback, 1994, p.193) – these activities may be, but do not necessarily need to be, undertaken strictly in the order listed. Many of them can be, and often are, carried out in parallel. As mentioned above (Section 2.2.1, page 20) it is also not uncommon for many iterations of these activities to occur throughout the course of an R&D project. As pointed out by Langrish *et al,* many of the inventive steps are embedded within the innovation process, not made prior to it or at its beginning (Langrish *et al,* 1972, p.7). Nevertheless, in order to make the discussion in the pages that follow more manageable, this section does separate the R&D process into three distinct segments: project initiation (activities 1-4), project management (activities 5-7), and project termination (Activity 8). Thus, although it might appear that these three stages are being presented as if they were the *beginning (invention)*, *middle (innovation)* and *end (widespread use)* of a traditional fairy story of successful innovation, it is important to stress that R&D is a complex web of many stories: apparent *ends* are often the *beginning* of another story, while other stories never seem to have an *end*. In short, the three phases can come in any order, and judgements about where one phase stops and another starts can vary considerably according to the perspective of the observer. At the same time, the way in which these activities are implemented may vary depending upon the strategic R&D approach adopted. For example, idea generation (activity 2) may still be seen as largely the function of the technical department (cf. first generation R&D), largely the function of

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[6] The creation of an idea and its reduction to practice to prove the principle involved (Rothwell and Zegveld, 1985, p.47)

[7] The commercialization of technological change (Rothwell and Zegveld, 1985, p.47)

the commercial departments (cf. second generation R&D) or a joint operation between technical and commercial departments (cf. third generation R&D). Product development (activity 5) may similarly be a single function operation, a multifunction operation or a transfunctional operation.

Whilst the literature usually links the practice of R&D to the exploration for new knowledge, the sections above have shown us that the exploitation of existing knowledge is also important in modern-day corporate R&D. And, increasingly, it is the exploitation of knowledge held external to the organization that is the focus of attention. As will be shown in the paragraphs that follow, knowledge acquisition and knowledge sharing are now viewed as important processes in the practice of corporate R&D, and the application of that acquired or shared knowledge is of fundamental importance throughout the task in hand, whether that be during project initiation, project management or project termination. That is, rather than the acquisition, transfer, and utilization of *information* (Burns and Stalker, 1961, p.153) it is the acquisition, sharing (transfer) and application (utilization) of *knowledge* that is now seen to be important in the effective practice of corporate R&D.

2.3.1 Project Initiation

Idea Generation (Activities 1 – 2)

Project initiation begins with an idea to be used or a problem to be solved. Whilst not always acknowledged previously, companies now do generally accept that ideas may come from anyone and anywhere (Leonard-Barton, 1995, p.10), from both within or without the organization. They may come from workers, staff, and managers, and from consumers and suppliers (Best, 1990, p.13). They may come from universities, research organizations, and government laboratories (Jewkes *et al,* 1958, p.127; Gibbons and Johnston, 1974, p.233). That is, it is not necessarily the institution which guides research to defined ends that provides the inventions upon which the eventual innovation is based (Jewkes *et al,* 1958, p.89). For example, in considering the R&D processes employed in companies gaining the UK Queen's Awards for technological innovation during the years 1966-67, Langrish and his co-workers came to the conclusion that, more often than not, technical novelty came from outside the organization (Langrish *et al,* 1972, p.8).

Many projects are the result of motivated staff producing and championing ideas in response to a perceived stimulus for change. That is, it is the 'exceptional and largely intuitive powers of individuals to identify unexpected variations' that appear to have been the source of much invention (Jewkes *et al,* 1958, p.120). Nevertheless, Quinn notes that 'the most innovative organizations' typically take a more proactive route to idea generation. Observing that scientific knowledge and technological advances from seemingly unrelated fields frequently interact to create totally new concepts or opportunities of importance to the enterprise (Jewkes *et al,* 1958, p.118; de Solla Price,

1975, p.22), he points out that these organizations often have active strategies to develop information for trading with a variety of external research or technology groups (Quinn, 1985, p.272).

From the perspective of the producing company, projects may be initiated in order to solve a particular problem (Tang, 1998, p.300), which may be customer, supplier or company related (Leonard-Barton, 1995, p.184). For example, projects may be initiated to meet unusual customer requirements, to replace raw materials no longer available on health or safety grounds or in general decline, or to fill a gap in the company's product or process portfolio. They may be initiated in response to an emerging market, a segmenting market, or a change in consumer requirements in a previously stable market (Best, 1990, p.14). Or they may be initiated specifically to combat competitor actions. Developing superior production-chain or distribution links are typical examples designed to meet this latter need.

According to Langrish *et al,* the most frequent single method of transfer of external ideas into organizations is via a person joining the firm (Langrish *et al,* 1972, p.9). Other common methods include previous or concurrent industrial or educational experience; commercial agreements (including take-overs and sale of know-how); literature searches; personal contact; collaboration with suppliers and customers; and information passed on by government agencies and consultants (ibid, p.79). Corporate innovations (as opposed to inventions) are then, in most cases, the result of the convergence of multiple ideas resulting from many strands of events (ibid, p.7).

Whilst noting that the relatively small numbers of innovations involving large changes in technology could be ascribed to the realization of the potential usefulness of a discovery (science-push, first generation R&D), Langrish *et al* observed that the clear identification of a need that could be met by the available technology (market pull, second generation R&D) was the highest common factor for successful corporate R&D (Langrish *et al,* 1972, p.8). They did, however, also note that it was not unusual for the eventual need to differ from the initial one, and that some innovations proceed, in the early stages, in a market environment which is indifferent at best, only coming to fruition by some combination of personal enthusiasm, organizational pressure, and sheer historical accident (ibid, p.50).

Langrish *et al's* work is essentially confirmed by the findings of Project SAPPHO (Scientific Activity Predictor from Patterns with Heuristic Origins) (Rothwell *et al,* 1974). Defining 'success' as a composite measure based upon (a) net monetary gain, (b) market share, and (c) alignment with company strategy, Rothwell and his co-workers compared paired 'successful' and 'unsuccessful' technological innovations in the chemical process and scientific instruments industries and showed that successful innovators out-performed their unsuccessful counterparts in respect of five competences: they had a much better understanding of continuing and changing user needs; made more use of outside technology and scientific advice; performed their development work more effectively, but not necessarily more quickly; gave the responsibility for project completion to more senior individuals with greater authority; and paid more attention to marketing and publicity (ibid, p.259). Although some inter-industry differences were commented upon – most notably the degree of risk-taking: successful instrument makers operated with technologies and in markets with which they were more familiar; whereas the most successful companies in the chemical industry were first to market, and employed more radical technology – similar

results were found in both industries. In respect of the R&D approach adopted, in 21% of the pairs studied market-pull was found to differentiate in favour of success, whereas in the remaining 79% of pairs there was no correlation between success and failure. In no case was technology-push found to differentiate in favour of success, or market-pull in favour of failure (Rothwell *et al,* 1974, p.277). It should, however, be pointed out that these authors were writing at a time when second generation, market-pull R&D was the corporate norm in the UK (Section 2.2.6, page 34 above). In contrast, an earlier study in the USA had noted that for a range of successful innovations 45% were primarily marketing-led, 30% were production-led, and 21% were technology-led (Myers and Marquis, 1969, p.39).

Rather than customers, suppliers, and other organizations merely supplying ideas for development, or, perhaps, participating in the innovation process of the producer of an innovation, von Hippel noted that, not infrequently, organizations other than the producer had first developed and actually applied an invention upon which the producer's 'innovation' was eventually based (von Hippel, 1988, p.4). By studying innovations in the scientific instrument, engineering plastics, and process equipment industries, he observed that these first innovators – his 'functional sources of innovation' – varied between industries. And, he advanced the proposition that the temporary profit or 'economic rent' that might be reasonably expected by these innovators in being 'first to market' could, by itself, explain these variations (ibid, p.5). More importantly, he suggested that by understanding how the expected innovation profits are distributed amongst the various functional sources of innovation, and how the distribution of these profit expectations might be shifted, it should be possible to understand how the distributed innovation process might best be managed (ibid, 1988, p.7). For example, if 'users' are more typically the

functional sources of innovation for a particular field of activity, an alternative proactive route for idea generation for the ultimate producer might be to look to the activities of those users known for their innovative capabilities. Such an approach is developed by von Hippel and his co-workers in the 'Lead User[8] Process' (von Hippel, 1978, p.39; von Hippel, 1988, p.106; von Hippel *et al*, 1999, p.47). This process involves the systematic task of identifying a target market and the type and level of innovations required by stakeholders within the company; learning about the relevant emerging technologies and leading-edge applications by networking with experts in the fields of interest; selecting promising innovations and ideas; and working with several lead users to design concepts that fit the company's needs (von Hippel *et al,* 1999, p.52).

From a technical point of view, learning from lead users gives the supplier a view of what *is* possible rather than what *might* be possible. From a marketing perspective, learning from lead users gives the supplier a better idea of what other customers may need in the future. More importantly, however, involving lead users in the idea generation stage reduces the path dependency of innovation (Section 2.2.4, page 27, above). Interestingly, lead users' rewards for participating in the process may be purely intellectual, since sharing the resulting intellectual property rights is not necessarily part of the commitment (von Hippel *et al,* 1999, p.54). What lead users do perhaps gain is additional knowledge and understanding of what the future might hold for each of them.

In general, product, process, and organizational forms are all areas ripe for innovations (Best, 1990, p.11; Utterback, 1994, p.vii), and, as shown by Utterback, often occur in that order (ibid, p.90). Modelling the dynamics of American industrial innovation, Utterback

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[8] Lead users are defined as 'those organizations or individuals that are many years ahead of market trends and have needs that go far beyond those of the average user.' (von Hippel *et al*, 1999, p.48)

describes three phases of innovation. In the first phase – the fluid phase – the introduction of an innovative product gives rise to a variety of similar products, since unencumbered by universal standards or by uniform product expectations in the market place, competitors experiment freely with new forms and materials. The rate of product innovation is high (Utterback, 1994, p.86). However, as the expectations of the market become more clearly defined, the bases on which product innovations can take place become fewer (ibid, p.82). Expected requirements tend to promote a predominant product design and, in consequence, the rate of product innovation decreases (ibid, p.83). In the second phase of innovation – the transitional phase – competition becomes based upon price, reliability and service (ibid, p.86). This spurs the move towards process innovations. Since process innovations are generally less easily copied, the market eventually tends to be dominated by those organizations having the most effective and efficient production facilities. The rate of process innovations decreases (ibid, p.88). The third innovation phase – the specific phase – commences when the industry reaches a point of stability in which there are only a few firms producing standardized or slightly differentiated products with stable sales and market shares (ibid, p.96). Utterback sees the move from product innovation to process innovation to standardization being, of necessity, accompanied by changes in the firm's organizational form: from entrepreneurial organic forms during the fluid phase designed for uncertainties in the market and technology (ibid, p.93); to intermediate forms in the transitional phase as the predominant design emerges and dictates operational rigidities (Utterback, 1994, p.96), to hierarchical mechanistic forms in the specific phase designed for the production of specific products at high levels of efficiency (ibid, p.91). In consequence, the sources of innovation change from industry pioneers and product users in the fluid phase, to manufacturers and users during the transitional phase, and often to suppliers in the specific phase (ibid, p.94).

Idea Screening (Activity 3)

It is not, of course, possible for an organization to act upon all of the ideas that might be advanced (Myers and Marquis, 1969, p.30). At some stage it becomes necessary for those deemed worthy to be progressed further, and those deemed less important to be abandoned. To this end, a number of companies operate a form of idea evaluation funnel whereby ideas are explicitly screened, first, against strategic and business objectives and, second, against technical feasibility and financial objectives (Walker, 1994, p.19). For example, will the product or process fit with or complement the existing business portfolio? Will the product or process deliver the required return on investment? Will the science or technology employed do what is expected of it within the time frame required? We should not, however, forget that there may be a third screening, a political or interest-based screening that encompasses the range of interests of importance to the actual decision makers. These interests include views concerning the 'proper way' in which the task should be carried out, the implications of the decision on the decision makers' roles or careers within the organization, and perceptions about what the decision might say to others (Thomas, 1994, p.83). Thus, both technological determinism and social choice issues may play a part in moving ideas forwards (ibid, p.3). And, when group-based rather than position-based decisions are made, negotiation and persuasion between conflicting viewpoints may be the order of the day (Kanter, 1983, p.48).

Concept Testing (Activity 4)

Following the idea generation and initial evaluation stages, concept testing and detailed feasibility studies are commonly undertaken in order to validate the choice between

various options, or even to determine if one option alone is appropriate. For instance, might the new product, process, or service be developed using an extension of an existing technique; a conjunction of existing techniques, products and processes; or techniques employed in related or unrelated fields of activity (Langrish *et al,* 1972, p.43); or is an entirely new approach required? Testing of these concepts is usually carried out by a small technical team but with some marketing involvement. Evaluation of the commercial feasibility of the options is essentially a marketing activity but with some technical input. Resources permitting, the preferred choice of most companies is to develop several options in parallel until the 'means' have been proven and the 'ends' are fairly clear (Allen, 1977, p.63; Pearson, 1991, p.21). Subsequent decisions can then be made on the basis of informed cross-functional understanding as the project progresses (Leonard-Barton, 1995, p.84).

Whilst such concept testing might be assumed free from partisan influence, the way in which individuals or groups interpret what is required, or implement what is thought to be required, may be open to a degree of political or social manoeuvring as proposals are, perhaps only subconsciously, evaluated in the light of individual and group, in addition to organizational requirements (Thomas, 1994, p.25). Whilst choices between sciences and technologies may originate with higher management, it is the lower echelons of the organization – whether organized by hierarchy or knowledge expertise – that are responsible for implementing those choices, and implementation choices may determine *which* science or technology is ultimately employed (ibid, p.214), and, indeed, *in what way* that science or technology is employed (ibid, p.218). At the same time, existing scientific and technological capabilities and competences may move the decision towards, for example, employing existing plant and machinery, especially if the organization has

invested considerable sums of money and training into the use of that equipment (Thomas, 1994, p.204).

Knowledge Processes

The acquisition of strategic knowledge is particularly important during the project initiation stage: there is the need to know what prior knowledge already exists regarding the subject of interest; what the likely advantages and difficulties might be in exploiting that knowledge; what expertise is needed for the evaluation of options; and what expertise might be needed to complete the chosen task. Sharing knowledge with others is also particularly important at this stage: both strategic and project-related ideas need to be shared so that the various options can be assessed by all of the parties involved; and the results of any feasibility studies need to be shared so that these ideas can then be promoted or terminated. The literature suggests a number of ways by which information, and the knowledge behind that information, might be acquired or shared. The sources typically used at this early stage of the R&D process include written communications such as patents, conference reports, reports in trade and academic journals and on the Internet; discussions with supply-chain contacts; technology in-licensing and outsourcing agreements; and community of practice networks (Mansfield, 1985, p.221). As will be shown in Chapter 3, whilst published sources might more strictly be said to yield information, personal communication is expected to enhance knowledge acquisition and sharing, since it offers the advantage of a two-way conversation, and thus allows context and understanding to be explored and shared. Again, it cannot be assumed that such knowledge and such information is free from personal or group bias. And, where knowledge acquisition is the purpose, it perhaps goes without saying that, whatever the

method employed, the estimated worth of any knowledge to be acquired needs to be assessed against the cost of acquiring that knowledge and the risks of inadvertently sharing competitive knowledge with the provider (Mansfield, 1985, p.221; Smart *et al*, 1999, p.109).

Technology in-licensing agreements are often viewed as offering a quick way of acquiring knowledge for upgrading products and processes. However, as Dickson and Hadjimanolis have pointed out, the exclusive use of licensors appears to have a negative effect on the wider learning and the accumulation of expertise of the firm (Dickson and Hadjimanolis, 1998, p.15). A major problem is that whilst in-licensing agreements transfer the information of how to do something, they do not necessarily transfer the knowledge behind what is to be done. Without the capacity to interpret information in a meaningful manner, the scope to learn is reduced.

Outsourcing has been encouraged to decrease the path dependency (Section 2.2.4, page 27) of innovation (Bowonder and Miyake, 1999, p.85). However, too much outsourcing can lead to the loss of key internal workers, together with their existing knowledge. This can lead to a company becoming ever more reliant on external R&D sources for its continued success. As a deliberate strategy, this might work well for the company (although not so well for its R&D employees). However, relationships with partners then become crucial. According to Quintas and Brauner, a key question for firms outsourcing their R&D is whether they retain the capability to understand and assimilate or absorb knowledge created externally, and also retain the ability to combine this with internal resources and capabilities (Quintas and Brauner, 1999, p.50).

Customer links are the backbone of sales and marketing operations. As noted above (Section 2.2.4, page 28), they are also important to R&D personnel as they can often highlight new (technical) ideas and possibilities. Whether these ideas are strategically important is another matter. What is important is that it is known that such possibilities exist. Major suppliers can also provide ideas for development. The problem in both cases is that this knowledge will undoubtedly be provided to competitors (Mansfield, 1985, p.221). Links with Standards and Trade Associations are useful for keeping up-to-date with current and possible future legislation that may impinge on the viability of current and possible future products and processes.

Whilst community of practice networks do aid in the acquisition and sharing of knowledge (Bowonder and Miyake, 1999, p.85), their purpose goes deeper than this. They enhance learning and build competencies (Powell *et al*, 1996, p.119; Echeverri-Carroll, 1999, p.298) and enable the search for new opportunities (Coulson-Thomas, 1997, p.207). Their importance is indicated by Huber's observation that people who are well networked in the technical communities (both within the firm and within the industry) can often provide the 'newly-seen-to-be-needed' technical knowledge more effectively than can a highly qualified technical expert who is not well networked (Huber, 1999, p.72). These informal networks, thus, represent an important intangible resource to the organization, a resource which is difficult for competitors to replicate (Hall, 1992, p.135; Conway, 1995, p.338). However, because they show no respect for organizational boundaries, they are seen by some to be contrary to the interests of the organization (Mansfield, 1985, p.223). They are also seen as inefficient since they do not necessarily relate directly to company strategy (Thomson *et al*, 1999, p.11). For these reasons, some organizations attempt to limit the external links of their R&D workers by, for example, limiting access to customers, and

removing support for attendance at seminars and conferences. However, companies that seek to control these informal knowledge networks may well be losing access to the latest ideas, thoughts and understandings of areas of technology that could be vital to their future. As Brown and Duguid point out:

> 'Cutting off the outflow can also cut off the inflow of knowledge. Living in a knowledge ecology is a reciprocal process, with organisations feeding into each other.' (Brown and Duguid, 1998, p.103)

Informal communication networks extend well beyond the realms of the organization to which a particular scientist or technologist may belong. What is interesting is that, although there is a degree of overlap, distinct differences have been observed between the social organization of the networks that occur in science and those that occur in technology.

Crane describes the social organization of specific research areas in science as 'social circles' which encompass 'invisible colleges' (de Solla Price, 1975, p.101). It is the invisible colleges that help to unify the areas and provide coherence and direction to their fields (Crane, 1972, p.138).

Invisible colleges in the UK have their roots in the informal 'club' that the London-based artisans and practitioners of science formed in the 17th century in order to promote and discuss their ideas, their problems, and their experimental findings. Initially, these amateurs, in modern terms both scientists and technologists, met informally within the chambers of the chief participants, within the shops of the instrument makers, and within the taverns (later coffee houses) that they frequented and used as a general post office. Eventually, meetings became more regular, and, with the granting of a Royal Charter, the 'Royal Society' was formed (de Solla Price, 1975, p.102). Today, the term 'invisible

college' would appear to be restricted to the open social group that forms between an 'elite of mutually interacting and productive scientists within a specific research area' (Crane, 1969, p.348).

Social circles form on the basis of members' interests rather than propinquity or ascribed status (ibid, p.348). There is no formal leadership (Crane, 1972, p.14). Each member is usually aware of some but not all other members. It is not necessary to know a particular member of the group in order to be influenced by him/her (Crane, 1969, p.348). And the exact boundaries of the circle are difficult to locate (Crane, 1969, p.348; Crane, 1972, p.13).

Crane suggests that the presence of scientists whose productivity in a particular field is sufficient to make them visible to most of those who enter the same field, even briefly, produces a social circle (Crane, 1969, p.349). And, in turn, the circle plays an important role in the normal growth of a research area and, ultimately, in the growth of scientific knowledge in general. First, interesting discoveries that provide models for future work attract scientists to a particular research area (Crane, 1972, p.40). Initially there is little or no social organization (ibid, p.172). Next, a few individuals of high potential develop a high degree of commitment to the area, and, as a result, are able both to direct the activities of others in the field, and to make it visible as a research area. This may be directly through their ability to set priorities for research, recruitment, or training; or indirectly through the influence of their research publications or presentations (Crane, 1969, p.341; Crane, 1972, p.40). The ties between high producing individuals and between these individuals and others in the circle are stronger than the ties between other members. Thus, social circles become orientated around these high producing individuals. The

central figures in these circles and some of their associates develop a kind of solidarity that is useful in building morale and motivation among all members of the circle, and an invisible college is formed (Crane, 1969, p.345; Crane, 1972, p.139). A period of normal science follows (Crane, 1972, p.172), and a degree of conformity may set in around the norms set by the invisible college (ibid, p.83). As the seminal ideas that form the bases of the research area become exhausted or become increasingly difficult to test due to the presence of anomalies that cannot be explained by the original model, new scientists are less likely to enter the area, old members are more likely to drop out (ibid, p.40), or researchers become more specialized and split from each other (ibid, p.83). Controversy may result between groups, or groups may become increasingly isolated from each other. The result is a gradual decline in membership in the original area (ibid, p.40). Thus, growth in scientific knowledge is cumulative – at least until the presence of anomalies – and follows a logistic curve in which scientific advance begins slowly, accelerates exponentially, and then declines (ibid, p.172).

At the same time, no research area is completely isolated from other areas (ibid, p.13). Members of a circle may be influenced by defectors – those who have left the area of interest – and by the publications of outsiders in general (Crane, 1969, p.341). Whilst ties between members of the circle and outsiders are generally weaker than those between members, they are numerous. Whilst most circles tend to be linked only to those to which they are most related, all fields are interlocked in a 'kind of honeycomb structure' (Crane, 1972, p.103). Thus, social and ideational links hold the various segments of scientific knowledge together and permit the diffusion of ideas from one area to another (Crane, 1969, p.349; Crane, 1972, p.13).

Crane suggests that the links with outsiders can be best understood with reference to the phenomenon of 'reference scattering' (Crane, 1969, p.349). And, she adds that both 'core' and 'scatter' are necessary for scientific advance: 'the former to permit scientific knowledge to cumulate and grow, the latter to prevent it from becoming a completely subjective, sect-like phenomenon' (Crane, 1969, p.350; Crane, 1972, p.114). If there were no core, scientific knowledge would be so scattered that it would be virtually impossible for one scientist to build upon the work of others (ibid, p.349). If there were no scatter, scientists would be divided into small groups, sharing the same interests, speaking only to each other, reading and citing only each other's work, and increasingly working in isolation from others.

Crane does not specifically talk about the role of industrial scientists. Although it is conceivable that some industrial scientists may form the nuclei around which scientific advance occurs, the main purpose of these scientists' working lives is to provide and apply scientific knowledge in response to the needs of their organizations, not necessarily to publish papers or bulletins for the benefit of the scientific community in general. In consequence, although some industrial scientists may be classed as 'high producers' in Crane's terms, the likelihood is that most, if included at all, will be amongst the 'lower producers'. It is also more likely that industrial scientists will enter a particular social circle later rather than earlier (Rappa and Debackere, 1992, p.214), either in response to a particular need of their organization, or because the developing field of science offers possibilities for organizational advancement. At the same time, the fact that industrial scientists are responsible, ultimately, for the production of some physical change in the world – a new product, a new production process, or a new method – means that their

networking actions may perhaps be closer to those of the technologists (or engineers) that Allen has studied (Allen, 1977, p.3).

Allen notes that the goals of technologists are very much in line with the goals of the organization – baring industrial espionage, both wish to develop products and processes that bring organizational success in the market place (ibid, p.38). At the same time, the career aspirations of technologist are very much tied to their activities within the organization (ibid, p.39). These facts, he suggests, work in two ways to inhibit the technologist from participating in informal technical communication channels outside the organization (ibid, p.40). First, the technologist is inhibited by the requirement that he work only on problems that are of interest to his/her employer, and, second, he/she must refrain from early disclosure of the results of his/her research in order to maintain his/her employer's advantage over competition. As Allen points out, both these constraints violate the scientific norms that underlie and form the basis of the invisible college – the requirements that science be free to choose its own problems; that the community of colleagues be the only judges of the relative importance of possible areas of investigation; and that the substantive findings of research should be fully assigned and communicated to the entire research community (Allen, 1977, p.41). The free and open communication that occurs between scientists is thus less likely between technologists (Rappa and Debackere, 1992, p.220).

The effect of this 'enforced localism' is to focus the technologist's attention inwards towards the technical information and knowledge that is held within the organization rather than outwards to the information and knowledge that is held by the external technical community (Allen, 1977, p.41). As such, internal communication is particularly important

between technologists (Allen, 1977, p.122). It was recognized that frequent links with more colleagues was more beneficial to performance than frequent contacts with just a few colleagues. And, for complex projects, links with colleagues outside of the project team were particularly important, since the inner team is unlikely to hold all of the information required to sustain itself and continue to work effectively (ibid, p.123).

Nevertheless, information from outside the organization is essential for keeping current with state-of-the-art ideas, products and practices (Allen, 1977, p.126; Rappa and Debackere, 1992, p.209). Normal staff turnover can help to transfer some information because a new employee can often bring in a new or different technology. But such a mechanism is perhaps not to be relied upon. As well as importing information with the new employee, the organization may also incur the export of some proprietary information with the loss of the old employee (Allen, 1977, p.142). Long-term consultants who understand the needs of the organization can provide some relevant information but are unlikely to be able to meet fully the organization's needs for communication with the outside world. Instead, technology-based organizations tend to rely on 'technological gatekeepers' to ensure that their personnel are kept aware of the results of research done elsewhere (ibid, p.141).

Technological gatekeepers are those individuals within the organization who make it their purpose to keep in touch with sources of technical information outside the organization. They understand at least a proportion of the more sophisticated technical journals, and can translate the information contained within these journals into terms that the average technologist can use (ibid, p.145). In addition to their many internal contacts, they also have a broad range of external contacts that they can turn to for help on an informal basis.

In turn, they tend to be those individuals to whom others frequently turn for advice. They are usually high technical performers (Allen, 1977, p.163) with high professional status (ibid, p.168), and they frequently occupy first-line supervisor roles (ibid, p.171). They generally attend and produce more papers for presentation at technical conferences (ibid, p.163).

Rather than the social circles of scientists with no particular organizational affiliation, technologists thus tend to form internal organizational networks, which are then connected to the outside world through these key individuals. Rather than information passing directly between the individual technologists of different organizations, external information passes to them indirectly through the technological gatekeeper (ibid, p.148). In larger organizations, information networks can become complicated, but frequently a gatekeeper network may form which assists information diffusion throughout the entire organization (ibid, p.162). These networks sometimes are, but may not necessarily be, aligned with the formal organizational groupings (ibid, p.155).

Rather than the social circles that develop purely between scientists, technologists may, as noted above (page 51), in addition to links with their technologist colleagues, also form links with customers; the sales representatives of other companies who would like to sell them components, subsystems, or instrumentation of use to their current project; and experienced consultants. They also typically contact government, non-profit, or university laboratories on an informal basis for ideas regarding solutions to specific problems (Allen, 1977, p.127). A technological community is thus more truly interdisciplinary in nature, whereas a scientific community is demarcated by its particular scientific boundary (Rappa and Debackere, 1992, p.211).

Finally, Debackere and his colleagues point out that the continuous quest for individual credibility in scientific networks leads to a constant battle over the ideas that should be seen as important to scientific debate (Debackere *et al,* 1994, p.23). In contrast, networks between technologists are designed to unite actors behind a particular problem. Whilst conflict may occur over the best way forwards, individuals are united in the end that they wish to achieve.

Debackere and his colleagues argue that different types of network evolve in a scientific community as a technology matures (ibid, p.23). Initially, a few researchers dedicate themselves to furthering a particular field of enquiry. Whether, or not, these pioneers are employed in academia or industry they start working on similar problems with similar ideas. They may do this with little support from their organizations or from their peers (ibid, p.27). By 'bootlegging' they proceed to the point where the promise of the idea becomes clear. Throughout this first phase, the community of scientists is concentrated among a small number of organizations, and the yearly increase in number of researchers into the field is fairly moderate. However, as the number of individuals working on the same problem area increases, a communication network emerges with ties that are much stronger than the ties binding the individuals to the organizations to which they formally belong. The norms of the scientific paradigm predominate. Information and knowledge is passed freely between participants (ibid, p.28) and the producers of science are also its judges and consumers (ibid, p.27).

Spurred on by the advances made by the initial workers, a very rapid increase occurs in the number of scientists active in the field. A second phase begins. The new community of scientists becomes more widely distributed across organizations, sectors, and countries.

Congresses are organized and journals are founded in order to steer the efforts being made. If the work of the new field of enquiry attracts commercial interest, some scientists may be recruited by industrial concerns, while those already working within industry may be allowed to devote their efforts openly to the new field. Other scientists may decide to become entrepreneurs and start their own organizations. As the community expands and spreads, it develops a powerful momentum derived from the force of its numbers and the ingenuity of its researchers working independently in laboratories world-wide. However, with this expansion comes the diminishing ability of researchers to communicate easily with one another. Whilst some information can be passed through the published literature, the constant flow of new and complex ideas calls for something more. The informal communication network or grapevine is born (Debackere *et al,* 1994, p.28). It is during this phase that a new industry may come into being or an old industry may restart its life cycle. In any case, a new technological paradigm is created. Usually, consumer preferences in the market are not sufficiently clear to allow organizations to give strict guidelines to their workers. As a consequence, the network of scientists remains intact and transcends academic and organizational boundaries. Open and speedy communication remains the norm, even though academic institutions and industrial organizations may seek to obtain property rights to their ideas.

However, as the industry grows further, consumer preferences become stabilized, and product requirements become clarified. As Debackere *et al* point out this is the stage where the selection processes for industrial and non-industrial research start to divide (ibid, p.29). Whilst academic researchers continue to work within the scientific paradigm, industrial scientists are bound by the technological paradigm (ibid, p.30). This requires an adherence to the norms of commercial exploitation, and specifically to rules that seek to

safeguard proprietary knowledge, wherever possible, from rapid diffusion (Debackere *et al,* 1994, p.24). Industrial scientists collectively stop forming an integral part of the scientific network. Some do, however, remain within that network on an individual basis (ibid, p.30). From these individuals, come the technological gatekeepers who continue to keep their organizations abreast of the latest ideas and views within the relevant sciences (ibid, p.34).

As the second phase progresses further, one of two paths may emerge. Scientists continue to make progress in solving the problems confronting them, allowing the community to institutionalize itself, or progress begins to slow down, forcing the community to contract and perhaps even return to the conditions prevailing in the first place. If the new scientific paradigm becomes legitimized and sustained, it will attract many more researchers. As some researchers begin to concentrate on particular areas within the original field of enquiry, strategic groups may form. Over time, this leads to further specialization, increasing isolation, and ultimately sterility as the linkages that encourage innovation eventually fade. It is Debackere *et al's* suggestion that such sterility may be prevented, or at least postponed, by new stimuli coming from the industry which is in a phase of maturity and which is increasingly dominated by demand-pull innovation. Although the R&D community of all scientists in a field may have long split up, the long-term vitality of both successor parts is thus very much linked (ibid, p.30).

2.3.2 Project Management

'Product' Development (Activities 5 – 7)

Development is about applying existing knowledge to exploit a new idea (Jewkes *et al*, 1958, p.204). It is the stage at which known methods are applied to that idea. It is the stage at which the task to be performed is more precisely defined, the aim more exactly set, the chances of final success more susceptible to measurement. And, it is the stage at which commercial considerations are more systematically examined; where the limits of feasibility imposed by the markets are narrowed down (ibid, p.18). Indeed, knowledge of markets, customers and suppliers, together with government legislation and regulation, is crucial *throughout* this part of the R&D process, and this is perhaps one reason why many Western companies have introduced 'matrix' management approaches, the expectation being that such approaches would more actively encourage the dissemination and integration of the knowledge necessary for successful project completion (Kanter, 1983, p.341; Best, 1990, p.259; Leonard-Barton, 1995, p.xv). As a consequence, where project teams formerly involved only members from the technical departments they now often involve people from across the organization's different functional groups. These teams are essentially non-hierarchical. They may include members from within the organization or from other organizations, the requirement being that these individuals have the relevant (or best possible) knowledge and experience for the job in hand. For example, user involvement may be useful in gaining insights into the application environment of the product or service (Leonard-Barton, 1995, p.94).

In the past, development teams have been organized either by product group or by functional group. As pointed out by Henderson, organization by product group focuses the energies of the organization on the customer and encourages rich communication across functions, but it often does so at the cost of a steadily eroding base of functional knowledge. Organization by function, on the other hand, ensures that the in-depth, specialized knowledge fundamental to long-term innovation is preserved and enhanced, but at the cost of a reduced focus on business priorities. By adopting matrix management and essentially organizing by both product and function, development teams are able to keep abreast of both the commercial and the scientific and technical advances of importance to the particular project (or projects) with which they are involved (Henderson, 1994, p.105). This does, however, mean that project teams now consist of people who are often not known to each other and who, both literally and figuratively, speak 'different languages'. In addition, many team members join and leave the team as their part in the project is being progressed. As well as managing the project from a 'technical' point of view – that is, designing and evaluating approaches, ensuring that adequate resources are made available, monitoring progress, redirecting resources, etc. – project leaders need also to manage people from a variety of backgrounds with many motives, interests, and world views (Thomas, 1994, p.236). Success perhaps comes to those who are able to encompass these views and use the conflicts that undoubtedly will occur to move the project forwards in interesting and radically different ways (ibid, p.238), to use conflict as a stimulus to innovation (ibid, p.241).

'Project Management' packages are often used in the West to aid resource allocation and task scheduling, for project monitoring and rescheduling of tasks when appropriate, and for calculating the various costs involved. Project management packages have also been used

by some Western organizations in an attempt to 'control' the R&D process. However, as Burton and co-workers point out, such 'control' is based on the assumption that the environment is predictable (Burton *et al*, 1988, p.113) and, even at the development stage, R&D is still an inherently uncertain process.

There have similarly been questions concerning the applicability of 'project management' approaches to more innovative or radical R&D, and even to the more basic needs of R&D such as the freedom to experiment. For this reason, some companies also implement or allow additional approaches outside their normal R&D practices. For example, many radically new products have been said to result from work carried out within 'skunkworks': small, flexible teams of scientists, technicians, and designers who work together to develop new products or processes from concept to commercial prototype stage 'with no intervening organizational barriers' (Peters, 1983, p.138; Quinn, 1985, p.271).

Other companies implement 'professional venture teams': they assign particular innovations to 'new venture teams' and give them 'the professional (engineering, marketing and financial) skills to see them through'. The thinking behind the process is that an innovation is like a baby: it needs a 'mother (champion) who loves it emotionally and will stay with it when others would give up; a father (authority figure with resources) who can support it; and pediatricians (experts) who can see it through technical difficulties' (Quinn, 1985, p.273). Skunkworks and professional venture teams are perhaps two examples of Kumpe and Bolwijn's fourth generation R&D practices (Section 2.2.4, page 28). A number of companies also allow their R&D staff to undertake 'work on the side' as long as this does not interfere with defined project targets. 3M's '15 percent rule' is a more formal approach, whereby R&D workers are *expected* to spend roughly fifteen

percent of their time dreaming up new products, new ways of lowering costs, or new ways of increasing productivity (McElroy, 2000, p.199).

Knowledge Processes

The acquisition of knowledge is an on-going part of this stage in the R&D process. However, whilst the techniques employed are the same as those used during the project initiation stage (Myers and Marquis, 1969, p.45), the emphasis is now upon the acquisition of project related knowledge. The sharing of this acquired knowledge within the project team is then crucial in order that everyone has an understanding of the wider picture, knows what is required of each and every one of them, knows what problems might and do occur, and knows the progress todate. Although such knowledge sharing is an integral part of team working, formal reporting procedures highlight major issues, such as changes in the overall goals of the project. Personal networks remain important to the individual R&D workers, but at this stage they are used for the exchange of general scientific rather than project-related knowledge (Myers and Marquis, 1969, p.45; Oliver and Liebeskind, 1997/98, p.77).

External knowledge sharing may result from team working when the team is formed as the result of a collaborative venture (Ray, 1998, p.163). Although collaborations have usually been observed to simply support transfers of 'commoditized knowledge' in the form of intellectual property rights and assets for commercial development (Oliver and Liebeskind, 1997/98, p.77), it is hard to see how success can be achieved without a degree of community working and knowledge sharing between the members of a collaborative team.

Although knowledge acquisition may be the corporate objective of alliance formation, knowledge sharing is more likely the R&D objective in such collaborations.

Whilst collaborative research involves the direct interaction between people working on a particular project and thus appears to offer the greater chance for such cross-boundary knowledge sharing (Becerra-Fernandez and Sabherwal, 2001, Table 3, p.42), this interaction is usually of short duration, so that the knowledge shared may be of limited extent. Cross-boundary personal networks, on the other hand, whilst not usually involving direct project interaction, can last for many years. The knowledge and understanding built up between the people in the network over these years may then go beyond that which may be built up from a collaboration of short duration.

Social strategies for promoting the spread of knowledge between communities have been described in terms of 'translation', 'brokering', and 'boundary objects' (Brown and Duguid, 1998, p.103). Organizational translators are individuals who frame the interests of one community in terms of another community's perspective. They need to have some knowledge and understanding of both communities. They also need to have the trust and respect of both communities. Knowledge brokers are those workers who actively participate in overlapping communities. Trust is then less of an issue, since knowledge brokers, unlike translators, are subject to the consequences of the messages they carry. Boundary objects may be physical objects, technologies, or techniques which are of interest to each community involved but which are used differently by each of them. 'Through them, a community can come to understand what is common and what is distinct about another community, its practices, and its world view. Boundary objects not only

help to clarify the attitudes of other communities, they can also make a community's own presuppositions apparent to itself' (ibid, p.103).

From experience, knowledge translators for R&D purposes are normally the senior technical staff with several years' commercial involvement. However, when the science is new, external mediators and consultants may be used. Knowledge brokers for research are usually the individual researchers. Knowledge brokers for development may theoretically be any member (scientific or commercial) of the development team. Boundary objects within R&D are typically the R&D process, the science and technology involved, and the organization's mission and strategy statements.

In adopting matrix management approaches, Western companies appear to be reflecting aspects of the Japanese 'rugby team' approach whereby the whole team moves forwards towards project completion despite the 'ball' passing from one 'player' to another. However, in working in this way, Western organizations do not have the support of Japan's accepted 'rules of the game' which institutionalize expectations that regular male employees can expect to spend many years working together in the same organization. As a consequence, they rarely, if ever, develop the close community relationships that emerge in Japanese organizations, relationships which can create considerable *esprit de corps* that helps to carry projects seamlessly across functional boundaries (Ray and Little, 2001, p.155). However, although expectations in the US, UK and other Western contexts normally afford rather more autonomy to the individual than would be considered appropriate in Japan, an emphasis on team production can yield dividends, notably in terms of increased flexibility, as the understanding held in common amongst team members creates a cushion for absorbing the effects of uncertainty. And, even in western contexts,

integrating the R&D function with the other parts of the organization does allow a more coordinated approach than was formerly the case – although there are limits: it is doubtful whether Western teams will ever share the same level of understanding that exists within the Japanese team that 'lives, works and dreams together' (Harvey-Jones, 1994, p.178).

2.3.3 Project Termination *('Activity 8')*

In one sense, projects never terminate as there are always improvements to be made or replacement products to be developed (Jewkes *et al,* 1958, p.200). And, even if a project fails to meet the desired objectives, it may be possible to use the results obtained at a later date or for a different purpose: for example, inventions that 'come before their time' may need to await further inventions (ibid, p.122); or a new product or process may be more successfully employed elsewhere (ibid, p.123). What is important is that failure is recognized as part of the process. Come what may, knowledge is created and lessons are learnt by R&D workers. As pointed out by Leonard-Barton, the problem is that this point is still rarely recognized by corporate management:

> 'IBM's famous 360 computer drew heavily on knowledge developed in a "failed" prior project ... Nevertheless, in most organizations, because previous projects were "unsuccessful," they become invisible, and managers delude both themselves and others about the debt owed to failures. Only development team members know how much they individually gained from previous unsuccessful explorations.' (Leonard-Barton, 1995, p.120)

2.3.4 A Summary of the Knowledge Types and Knowledge Processes used in the Practice of R&D

Table 2.3.1 (below) provides a summary of the main types of knowledge and the predominant knowledge processes used during the various stages of the R&D process. Context, in the form of the particular activity involved, would appear to affect knowledge creation in corporate R&D.

TABLE 2.3.1: THE R&D PROCESS: KNOWLEDGE TYPES AND KNOWLEDGE PROCESSES

Activity	Knowledge Types	Knowledge Processes
Project Initiation	Basic scientific and technical knowledge. Commercial knowledge, particularly user knowledge and knowledge of competitors' activities.	Knowledge acquisition, sharing, evaluation and integration for idea generation. Knowledge entrepreneuring for idea promotion. Knowledge creation through knowledge combination, experimentation and exploration.
Project Management	Scientific and technical knowledge, particularly related to design and manufacturing. Commercial knowledge, particularly marketing, procedural, and legislative knowledge. Project and team skills.	Project related knowledge acquisition, sharing and integration, largely through team working. Knowledge creation mainly through knowledge application and adaptation.
Project Termination	Scientific, technical and commercial knowledge, internal and external to the company.	Knowledge renewal and consolidation to yield understanding and learning.

2.4 Conclusion to the Chapter

This chapter has aimed at deconstructing some of the complexity associated with the interrelationship between corporate R&D and the context in which that R&D takes place. Each respective R&D generation discussed in Section 2.2 represents a simple explanation of what was considered important at the time. As the history of corporate R&D has unfolded, different factors have vied for the attention of policy makers. However, R&D is a complex process and, as the chapter has sought to show; simplistic explanations only form part of the picture – although they can be a very important part of the picture.

For example, if we adopt the idea that basic science provides the fountain from which new ideas flow, which is the essence of first generation R&D, commercial investment in invention might be a matter of replicating university-style basic research in a corporate setting – perhaps in a setting detached from the cut and thrust of daily business imperatives (as suggested by skunkworks). Under such a science-push model, assessing the viability of a proposed research agenda relies heavily on the authority of scientific assessments. Nevertheless, in a commercial environment there is always scope for economic, political and other interests to lobby for their preferred interpretation of what might be possible. Indeed, second generation R&D seems to strengthen the power of those from outside the technical sphere. And, the idea that *necessity* is often the *mother of invention*, inherent in the second generation approach, shifts the focus of attention from what might be possible to what is 'needed'. In this respect, it can be said that corporate strategy seeks to reconcile two continually changing forces: science is pushing, whereas needs are pulling.

Accordingly, third generation R&D might be seen as the fulcrum in the push/pull seesaw –

although the fulcrum need not be in the middle and the force needed to gain leverage can vary considerably. Nevertheless, no firm is an island.

The tendency to view the organization as a self-contained entity often lends an unwarranted solidity to the concept of organizational boundaries, resulting in the view that the organization is a self-contained thing that can be treated as an object in its own right. Yet, organizational boundaries can be extremely ambiguous and permeable to the movement of people and ideas. The context in which an organization operates enables and constrains its practices. Fourth and fifth generation approaches to R&D accept this, and recognize that activities beyond the organization can have significant implications for internal events. However, whilst fourth generation R&D seeks to 'manage' these activities, fifth generation R&D appears to seek advantage by facilitating the cross-boundary networking activities that are an integral part of how individuals act out their everyday lives.

Organic networks of the type implied by fifth generation R&D involve complex interactions. Although it might be possible to map some aspects of network-related activities, it is not possible to reduce the influence of networks to cause-and-effect connections. Everything is connected to everything else, and changing one thing can have non-linear consequences. On occasions, a small event can contribute to considerable consequences. Shared experience, among people who come to know each other well, shapes the significance that people attach to information that flows in networks: trusted connections that link powerful people can mean that small amounts of information contribute to big differences. Moreover, as we will see in the next chapter, it is not

possible to map what Michael Polanyi called the tacit integration of 'clues', which render information signals meaningful.

Clearly, networks facilitate information flows; but information is only part of the picture – no message can read itself and access to the right information is not the same as knowing what it means. Thus, fifth generation R&D certainly embraces the concept of information super-highways, but the extent to which they are useful to innovating organizations is shaped by what is happening in the here-and-now of everyday practice. And this concern with practice re-anchors our enquiry in the activities and processes of the innovating organization.

Section 2.3 considered organizational activities in terms of the principal stages of the R&D process. R&D projects have a *beginning*, *middle* and *end*, but not necessarily in that order and not necessarily within the organization. Some projects start elsewhere, while others falter in the middle or are finished by competitors. In many cases, what was achieved, along with the merits or otherwise of doing things differently, is contested by different parties. Any claim of cause and effect per force involves the imposition of rationality on experience, but this begs key questions: whose rationality and whose experience?

Roughly speaking, views about knowledge and knowing have been divided into two categories according to whether of not they see the subject as relatively straightforward or highly problematic. Arguably, Knowledge Management falls into the former category: tacit knowledge can be converted into information (i.e., 'explicit knowledge') and 'managed' (McInerney and LeFevre, 2000, p.1). Similarly, the five generations of R&D are characterized by a relatively unproblematic approach to knowledge: knowledge only

becomes awkward because of its absence. If that absence can be fixed by scientific discovery, responding to a need, the integration of business activities, fourth generation collaboration, or fifth generation virtual networking, the problem goes away. Thus, to achieve 'success', corporate strategy merely has to transport the right information to the right place and wait for everything to take care of itself – or so the argument might run.

Alternatively, there is a different view that sees knowledge as highly problematic (Hull, 2000, p.64). Knowledge is not a transferable commodity and communication is not a form of transport. Instead of being viewed as an abstract entity that is separate from the knowing subject and the messiness of power relations associated with a specific context, this second view makes *knowers* – the people who know things – the focal point of attention. If we are to begin to consider the issues raised by this second and more challenging domain, it is necessary to extend our literature review beyond the simplistic view of 'knowledge as information'. Accordingly, the next chapter explores these issues and reaches into the second domain by considering more complex perspectives on the processes by which people know how to do things in practice.

3 KNOWLEDGE CREATION: A LITERATURE REVIEW

3.1 Introduction

It was noted at the end of Chapter 2 that the R&D Management and much of the Knowledge Management literature has a tendency to treat the concept of 'knowledge' in a rather simplistic way. From this perspective, knowledge is viewed as an object that can be acquired, shared, applied and even created via a simple transfer mechanism. That such is not the case is perhaps evidenced by the consensus that technology transfers are rarely the simple processes they are initially expected to be: the transfer of plant (machinery and equipment) and written operating procedures are rarely sufficient to convey the knowledge held by the plant operators of the sourcing department, knowledge that is often crucial in keeping that plant operating smoothly; neither are they generally sufficient to provide the in-depth knowledge needed for the continued development of that plant. Before reviewing the literature on knowledge creation, Section 3.3 of this chapter therefore looks at the nature of knowledge to see why knowledge may not be the transferable commodity that it is often assumed to be, and why, even if knowledge can be transferred, verbal communication is not always the form of transport necessary. One of the conclusions of this section is that, in a purist sense, it is only information that can exist independently and which can thus be directly transferred. Knowledge acquisition or knowledge sharing – with no guarantee that the knowledge acquired or shared is the same for all parties – then results from the same or similar interpretations of this information, brought about as the result of a shared or similar understanding of what is meant by the information undergoing transfer. As noted in Chapter 1 (Section 1.4, page 11), references to knowledge

acquisition, knowledge sharing, and knowledge transfer in this thesis should be understood with this point in mind.

The importance of creating, sharing, and leveraging knowledge in organizations has been observed by a number of authors (see Becerra-Fernandez and Sabherwal, 2001, p.24). However, in an R&D context, the terms creating, sharing, and exploiting knowledge are more often used. In general, this thesis chooses to use the terms creating, sharing and applying knowledge as it is felt that these more accurately describe the activities under consideration. In particular, the term 'exploitation' suggests to the present author the aggressive promotion of particular items of 'knowledge'. In contrast, this study is more concerned with the application of knowledge relevant to the task in hand.

There are also a number of reports in the literature that refer to the need for knowledge dispersion or diffusion, and to the fact that dispersed or diffused knowledge is only of use if it is first absorbed or integrated (respectively, Tang, 1998, p.301; Polanyi, 1966, p.6). These processes have, in part, been assumed as fundamental activities in the knowledge acquisition, knowledge sharing, and knowledge application processes described in this thesis. It should, however, be noted that the use of the terms knowledge dispersion and knowledge diffusion also implies the assumptions associated with the more general use of the terms knowledge acquisition and knowledge sharing outlined above. Once again, it should not be assumed that the knowledge provided by the provider is the same as the knowledge received by the receiver. Indeed, different interpretations of the same 'piece' of knowledge may spark innovative thinking.

There are three models of organizational knowledge creation that have been variously suggested in the Knowledge Management literature. One of these models looks at the context within which knowledge is being created, whilst the remaining two refer to the actual knowledge creation process. In addition, whilst many authors refer to the contributions made by Michael Polanyi, they fail to acknowledge that Polanyi, himself, offers us a model of knowledge creation which is worthy of consideration. Section 3.4 in this chapter outlines the main points of these models.

Specifically, Section 3.4.1 looks at the work of Michael Gibbons, Camille Limoges, Helga Nowotny, Simon Schwartzman, Peter Scott, and Martin Trow as described in their book *The New Production of Knowledge* (Gibbons *et al*, 1994). These authors identified a new form of knowledge production (knowledge production in the context of application) that they saw as emerging alongside the traditional form (knowledge production in a disciplinary context). They termed the new form Mode 2 and the traditional form Mode 1. They suggested that Mode 2 knowledge production would have profound effects upon not only the way in which knowledge would be produced, but also upon what knowledge would be produced. However, as will be shown in Chapter 6, the present thesis suggests that these speculations are not necessarily consistent with practice.

Section 3.4.2 summarizes the model of organizational knowledge creation suggested by Ikujiro Nonaka (Nonaka, 1994) which was developed further in his book with Hirotaka Takeuchi: *The Knowledge-Creating Company: How Japanese Companies Create the Dynamics of Innovation* (Nonaka and Takeuchi, 1995). This model was particularly influential during the latter half of the 1990s because, referring to Michael Polanyi's work, it emphasized the importance of tacit knowledge, something that Western companies had

previously paid little heed to, assuming instead that all relevant knowledge could be expressed explicitly and stored in company databases (Chumer *et al,* 2000, p.xvii). However, a problem with this model is that it relies upon successive conversions between tacit knowledge and explicit knowledge, of the individual and group forms, and thus relies upon the assumption that knowledge is, in effect, an object that can be separated from context. As implied above (page 76), whilst this might apply to information, it is not something that can be guaranteed where knowledge is concerned. In addition, by separating knowledge into tacit and explicit forms, these authors do not appear to have taken on board Polanyi's assertion that all knowledge contains a tacit dimension.

Section 3.4.3 outlines the model of Scott D. N. Cook and John Seely Brown and described in their paper *Bridging Epistemologies: The Generative Dance between Organizational Knowledge and Organizational Knowing* (Cook and Brown, 1999). Cook and Brown reject the notion of knowledge conversion proposed by Nonaka and Takeuchi and suggest a model based upon a pluralist framework which differentiates between different categories of 'knowledge tools' that are possessed, which are used in the 'active process of knowing'. The generation (creation) of new knowledge and new knowing is then seen as a possible result of the interplay between knowledge (as a tool of knowing) and knowing (as an aspect of our interaction with the social and physical world). In one respect, Cook and Brown's approach might be taken to reflect what actually happens in practice: that is, we use the knowledge available to us at the time to carry out the task we are given. In addition, it does emphasize the importance of knowing. However, by treating the four forms of knowledge indicated by the tacit-explicit and individual-group dimensions as distinct entities in themselves, Cook and Brown also have not remained true to Polanyi's original explanation of knowledge.

Section 3.4.4 looks at Michael Polanyi's work as described in his book, *The Tacit Dimension* (Polanyi, 1966). Although Polanyi's arguments adopt the perspective of the individual, as will be shown in Chapter 6 of this thesis, they nevertheless may be used to develop further insights into the knowledge creation processes within corporate R&D. Polanyi describes personal knowledge creation as a process of emergence. He shows us that by exercising our tacit powers of knowing we are able to assimilate sets of particulars to form an interpretation of the universe which is unique to ourselves, an interpretation which changes as we learn and understand more about the world in which we live.

Polanyi's work outlined in this chapter forms part of his studies into the philosophy of science. Whilst an investigation into such a philosophy is not the purpose of this thesis, some reference should perhaps be made to the ways in which philosophers have viewed the growth of knowledge within the scientific community, since such an exercise may perhaps throw some light on the way in which scientists think – or at least on the way in which philosophers of science believe they think – and, hence, on scientists' ways of working. Section 3.2 attempts to do this, although it perhaps goes without saying that the section can offer only a very brief and simplistic sketch of a field of work that is vast and ongoing.

Section 3.5 summarizes the main points of the Chapter.

3.2 The Growth of Scientific Knowledge

Debate in the twentieth century centred around two differing philosophical standpoints, summarized by Lakatos as 'science: reason or religion' (Lakatos, 1970, p.91). Essentially, the argument was between the growth of scientific knowledge as a process of conjecture and refutation (Popper) and the growth of scientific knowledge as the result of informed scientific consensus (Kuhn). Whilst Kuhn has generally been acknowledged to have won the debate (Fuller, 2003, p.4), as noted below, Popper's views perhaps still play some part in normal scientific practice.

For the most part, Popper and Kuhn work from similar premises. For example, they both accept that scientists necessarily develop their ideas within a definite theoretical framework (Kuhn, 1970b, p.242; Popper, 1970, p.51); they both reject the view that science progresses only by accretion and emphasize instead the revolutionary process by which an older theory is rejected and replaced by an incompatible new one (Kuhn, 1970a, p.1); and they both underscore the role played in this process by the older theory's occasional failure to meet challenges posed by logic, experiment, or observation (ibid, p.2). They both also reject a number of classical positivism's most characteristic theses. For example, they both emphasize the intimate and inevitable entanglement of scientific observation with scientific theory; they are both sceptical of efforts to produce any neutral observation language; and they both insist that scientists may properly aim to invent theories that *explain* observed phenomena and that do so in terms of *real* objects (ibid, p.2, italics in original). Nevertheless, as will be shown below, there is a fundamental difference between the ways in which these two philosophers view discovery and the consequent advancement of science.

Francis Bacons' advice to scientists was to study nature by collecting related observations with a view to discerning patterns of occurrence that call for explanation (Sheppard, 1999, p.6). As stated by Russell:

> 'In arriving at scientific laws there are three main stages: the first consists of observing the significant facts, the second in arriving at a hypothesis which if it is true would account for those facts, the third in deducing from this hypothesis consequences which can be tested by observation' (Russell, 1931, p.58).

Thus, scientific advance is assumed to be a logical process involving observation, hypothesis formation by induction, deduction from the formed hypothesis, and the testing of that deduction.

Popper's contribution to this reasoning was to emphasize that no matter how many times we make logical deductions from a hypothesis and test them to be positive, we can never be sure that there are not some other logical deductions that might prove negative. That is, in themselves, new observations which confirm a hypothesis cannot constitute reliable verifications of the hypothesis (Popper, 1963. p.55). Instead, we should look for new observations which *falsify* the hypothesis, since these will require a new theory to be devised, and in so doing we take a logical step forward (ibid, p.69). Thus, scientific advance becomes a logical process based upon conjecture and refutation (ibid, 1963, p.43). Popper's advice to scientists is that they should use their imagination to select an hypothesis, and should then continually seek to falsify it, since in so doing they may learn more from their mistakes. As he states:

> '[Conjectures] can never be positively justified; they can be established neither as certainly true nor even as 'probable' … Criticism of our conjecture is of decisive importance: by bringing out our mistakes it makes us understand the difficulties of the problem we are trying to solve. This is how we become better acquainted with our problem, and able to propose more mature solutions: the very refutation of theory – that is, of any serious tentative solution to our problems – is always a step forward that takes us nearer to the truth.' (Popper, 1963, p.xi)

Whilst accepting that many research *problems* may proceed via Popper's hypothetico-deductive form, Kuhn rejects falsification as the means for advancing scientific *theory*. He suggests that the scientist's object when undertaking 'normal research' [9] is to solve a 'puzzle', and existing theory is required to define that puzzle and to 'guarantee' that it can be solved (Kuhn, 1970a, p.5). Since, in a scientific context, no puzzle-solving enterprise can exist unless the practitioners of the particular science involved share criteria which, for that group and for that time, determine when that puzzle is solved, any 'failure' on the part of the individual puzzle-solving scientist is, at least in the first instant, simply a failure on the part of that scientist, and not a failure of the current theory of that science.

Kuhn further points out that whilst 'falsification' and 'refutation' are antonyms of 'proof', they are drawn principally from logic and from formal mathematics. When scientific theories are being propounded, he suggests that 'arguments are seldom so apodictic'.

> 'All experiments can be challenged, either as to their relevance or their accuracy. All theories can be modified by a variety of *ad hoc* adjustments without ceasing to be, in their main lines, the same theories.' (Kuhn, 1970a, p.13)

Indeed, it is by challenging observations or adjusting theories that scientific knowledge grows during the course of normal research (ibid, p.13). Only when a crisis develops – for example, repeated failure by the most brilliant professionals to match theory with the natural world – may the failure that had previously been personal come to be viewed as a possible failure of the theory being applied (ibid, p.7). Thus, with or without tests, a

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[9] According to Kuhn, normal research is the 'generally cumulative process by which the accepted beliefs of a scientific community are fleshed out, articulated, and extended' (Kuhn, 1970b, p.250). Normal research involves scientists and technologists who are concerned with three classes of problems: determination of significant fact; matching of facts with theory; and articulation of theory (Kuhn, 1962, p.34); problems which are propelled by the desire to be useful, the hope of finding order, the drive to test established knowledge, or simply the excitement of exploring new territory (ibid, p.37). Whether, or not, normal research differs from any other form of research, the problems ascribed by Kuhn to normal research are essentially the problems with which this current thesis is concerned.

puzzle-solving tradition can prepare the way for its own displacement (Kuhn, 1962, p.5). Kuhn's proposition is then that only when a theory is in crisis, will a period of 'extraordinary research' be encouraged, invoking a fundamental rethink of the underlying scientific principles, and in so doing produce a result that may lead to the rejection of the existing theory in favour of another, and even to the rejection of one way of thinking over another – a paradigm change or scientific revolution. The criteria with which scientists determine the validity of an articulation or an application of an existing theory are then not by themselves sufficient to determine the choice between competing theories, since the problem of theory choice cannot rely on logical criteria that are applicable in full only when a theory can already be presupposed (ibid, p.19). Instead, Kuhn sees the rejection of a previously accepted theory and the decision to accept another as 'an act of judgement involving the comparison of both theories with nature *and* with each other' (ibid, p.77, italics in original). Thus, 'given examples of what a scientific theory does and being bound by shared values to keep doing science, one need not also have criteria in order to discover that something has gone wrong or to make choices in case of conflict' (Kuhn, 1970b, p.275).

In practice, this means that a scientific community will rarely embrace a new theory unless that theory has solved all, or almost all, of the quantitative, numerical puzzles that had already been treated, although not necessarily solved, by its predecessor (Kuhn, 1970a, p.20). And even then, for a period of time, there may remain within that community a group of scientists who remain loyal to the old theory, in the hope that further adaptation of that theory may account for the anomalies that have accrued:

> 'For a man trained as a puzzle-solver will wish to preserve as many as possible of the prior puzzle-solutions obtained by his group, and he will also wish to maximize the number of puzzles that can be solved.' (Kuhn, 1970a, p.21)

At the same time, simplicity, precision, and congruence with the theories used in other specialties are all of value to the scientist during decision-making. However, these factors may not all dictate the same choice, nor will they necessarily be applied in the same way between specialties. When this is so, Kuhn suggests that group unanimity is of paramount importance (Kuhn, 1970a, p.21).

To Lakatos, this statement of group unanimity suggests that theories which inspire scientific revolutions or paradigm changes are the result of 'mob psychology' (Lakatos, 1970, p.178). To the present author, it is more a case of informed consensus based upon the respective merits of conflicting paradigms to explain the observations made of nature as they exist at the time; not necessarily a strictly logical process, but perhaps a rational one, knowing that there is much that is still unknown. This latter view is perhaps the point that Kuhn makes in his *Reflections on my Critics* (Kuhn, 1970b, p. 260). Whilst, on the surface, Lakatos' proposals outlined below might suggest a more specifically logical approach to discovery and scientific advance than do those of Kuhn, Lakatos is perhaps wrong to suggest that 'in Kuhn's view there is no logic, but only psychology of discovery' (Lakatos, 1970, p.178).

Lakatos criticizes Kuhn's arguments against falsification. Whilst he accepts that these arguments do apply to 'naïve falsificationism', adopting Popper's views and building on Popper's work, Lakatos asserts that they do not apply to a more sophisticated form of falsificationism (ibid, p.93). Sophisticated falsificationism retains the 'code of honour' that scientific honesty consists in specifying, in advance, an experiment such that if the result contradicts the theory the theory has to be given up (ibid, p.112). However, it makes allowance for the fact that scientists necessarily employ experimental techniques that may

be based upon fallible theories, and that they accept these fallible theories in a given context as *unproblematic background knowledge* for the purpose of testing the theory of interest (Lakatos, 1970, p.106). In consequence, if falsification occurs, it allows for the fact that this may be due to an error in experimental technique or possibly an error in some other *background knowledge,* which will then need to be investigated further before rejection of the theory should be made. It also accepts the fact that one single observation may be the stray result of some trivial error rather than an error of the theory, and prescribes some safeguards to overcome such a problem; the simplest being to repeat the experiment (ibid, p.107); another being to 'fortify' the potential falsifier by a 'well-corroborated falsifying hypothesis'. By separating rejection from disproof, sophisticated falsificationism ensures that theories are not eliminated prematurely (ibid, p.109). But, by doing so, it introduces decision-making into the process (ibid, p.112). And, decision-making incurs risks, so, how then might these risks be minimized?

In contrast to Popper, who construes 'falsification' as the result of a 'dual between theory and observation, without another better theory *necessarily* being involved' (ibid, p.181, italics in original), Lakatos suggests that an existing theory is 'falsified' if and only if another theory has been proposed such that the latter theory (a) predicts novel facts, (b) explains all the un-refuted content of the previous theory, and (c) has excess content, some of which has been corroborated (ibid, p.116). Whilst accepting that all theories, even those that have corroborated counter-evidence, may be adjusted and made acceptable by the addition of auxiliary hypotheses, in line with Popper, Lakatos suggests that 'saving a theory with the help of auxiliary hypotheses which satisfy certain well-defined conditions represents scientific progress, but saving a theory with the help of auxiliary hypotheses

which do not, represents degeneration' (Lakatos, 1970, p.117). The aim, of course, is to progress. Thus, Lakatos states:

> 'Einstein's theory is not better than Newton's *because* Newton's theory was refuted but Einstein's was not: there are many known 'anomalies' to Einsteinian theory. Einstein's theory is better than – that is, represents progress compared with – Newton's theory *anno 1916* ... *because* it explained everything that Newton's theory had successfully explained, and it explained also *to some extent* some known anomalies, and, in addition, forbade events like transmission of light along straight lines near large masses about which Newton's theory had said nothing but which had been permitted by other well-corroborated scientific theories of the day; moreover, *at least some* of the unexpected excess Einsteinian content was in fact *corroborated* (for instance by the eclipse experiments). (Lakatos, 1970, p.124, italics in original)

Lakatos' proposals mean that any scientific theory has to be appraised with its auxiliary hypotheses, its initial conditions, and any 'certain conditions', together with its predecessor theories, in order that the change brought about by the new theory be assessed (ibid, p.118). And, importantly, the elimination of the predecessor by its antecedent is brought about through defined rules which are not those described by naïve falsification. As Lakatos states, 'falsification in the sense of naïve falsificationism (corroborated counter-evidence) is not a *sufficient* condition for eliminating a specific theory: in spite of hundreds of known anomalies we do not regard [a theory] as falsified (that is eliminated) until we have a better one. Nor is 'falsification' in the naïve sense *necessary* for falsification in the sophisticated sense. Science can grow without any 'refutations' leading the way' (ibid, p.121). Thus:

> 'We never reject a specific theory simply by *fiat*. If we have an inconsistency ... we do not have to decide which ingredients of the theory we regard as problematic and which ones as unproblematic: we regard all ingredients as problematic in the light of the conflicting accepted basic statement and try to replace all of them. If we succeed in replacing some ingredient in a 'progressive' way (that is, the replacement has more corroborated empirical content than the original), we call it 'falsified'.' (Lakatos, 1970, p.125, italics in original)

In a similar way, in deciding between which of two mutually inconsistent theories should be eliminated, Lakatos states:

> 'One had to try to replace first one, then the other, then possibly both, and opt for the new set-up which provides the biggest increase in corroborated content, which provides the most progressive problemshift' (Lakatos, 1970, p.130).

These views would, at least to the present author, appear to have some similarities with Kuhn's views expressed above (page 84); the difference being that for Lakatos the acceptance of a new theory is more specifically based upon whether the new theory represents a progression by way of defined criteria.

In pursuing a particular research programme, Lakatos suggests that scientists are then not necessarily irrational when they tend to ignore counterexamples. They may be assuming that their experimental results are unreliable (Lakatos, 1970, p.176), or that the discrepancies that exist between the experimental results and theory are only apparent and will disappear with the advancement of understanding (ibid, p.177). As he says, 'Popper is right in stressing that the dogmatic attitude of sticking to a theory as long as possible is of considerable significance, [since] without it we could never find out what is in a theory … and in consequence no theory would ever be able to play its role of bringing order into the world, of preparing us for future events, of drawing our attention to events we should otherwise never observe' (ibid, p.177). However, as he also points out, this is a view that would appear to contradict Popper's comments elsewhere (Lakatos, 1970, p.177, footnote 3; and, for example, page 86 above).

Polanyi would appear to take a similar attitude to Kuhn as regards 'falsification' and might therefore, likewise, be criticized by Lakatos. Noting that an apparent falsification can never be totally decisive (Polanyi, 1958, p.316), he states that, in practice, scientists do not,

and should not, immediately reject a theory because of an apparent anomalous observation, provided that the theory is strongly supported on other grounds (Polanyi, 1958, p.20). So, on the practical aspect of theory rejection, Polanyi, Lakatos, and Kuhn would appear to agree, although Popper might not. Polanyi, additionally suggests that, in any case, scientists do not explicitly attempt to falsify their theories, 'for to have found one of promise is an achievement in itself which can be enjoyed permanently' (ibid, p.173).

Polanyi, like Kuhn, also notes that personal judgement forms an essential part of science since 'there are always some conceivable scruples which scientists customarily set aside in the process of verifying an exact theory' (ibid, p.20). But, in addition, Polanyi believes that discovery is about something more than judgement. It is about a deep personal appreciation of the problem to be solved and about the use of intuition in finding the solution (ibid, p.120). As Drusilla Scott points out, 'while induction and deduction make a tidy logical formula into which philosophers have fitted discovery', Polanyi, as a scientist of eminence, 'knew that this was not what discovery was like' (Scott, 1985, p.30). 'The beginning is not like Russell's first stage; it is a vague sense of a problem, which draws the scientist into a personal obsession in searching for the solution. This carries him through the patient meticulous work, the setbacks and disappointments, till a sudden flash of illumination, an imaginative leap, may show the answer. And the answer is an understanding of an aspect of reality, which may not be experimentally testable for years, and may have unpredictable consequences. It does not fit the rules at all' (ibid, p.31).

In line with Kuhn's view of a scientific paradigm, Polanyi also sees science as being pursued and transmitted to succeeding generations 'only within an elaborate system of traditional beliefs and values' (Polanyi, 1962, p.70). However, rather than Kuhn's

paradigm shifts and scientific revolutions, Polanyi sees this 'system of tradition' as, itself, a 'dynamic entity which is dependent upon constant self-renewal through the originality of its followers' (Polanyi, 1962, p.72). In this respect, Polanyi is perhaps closer to Popper and Lakatos, than Kuhn.

Also like Kuhn, Polanyi recognizes the importance of group unanimity. And he suggests the form that this unanimity might take. It is a unanimity based upon the 'free cooperation of independent scientists, coordinating their activities through a process of 'mutual adjustment of independent initiatives' (ibid, p.54) in relation to criteria laid down by the scientific community at large (ibid, p.57) – 'A Republic of Science' (ibid, p.54). Whilst the scientist's choice of problem may be said to have an economic character in that decisions are designed to produce the highest possible result by the use of a limited stock of intellectual and material resources (Polanyi, 1962, p.56), the depth of a problem and the importance of its prospective solution are primarily assessed by reference to professional standards of scientific merit. These are standards which depend upon *plausibility* in relation to current scientific opinion about the nature of things (ibid, p.57, italics added); *scientific value* based upon perceived accuracy, systematic importance, and intrinsic interest of the subject matter; and *originality* assessed by the degree of surprise which its communication should arouse among scientists (ibid, p.58, italics added). Although Lakatos might still see this as a form of 'mob psychology' this is not the view held by the present author. As Polanyi notes, whilst plausibility and scientific value tend to enforce conformity, it is the value attached to originality that encourages dissent (ibid, p.58).

Rather than the traditional view of scientists rejecting all authority, it is Polanyi's view that scientists are bound by the authority of the scientific community to which they belong

(Polanyi, 1962, p.68). It is the existence of this community authority that fosters, controls and protects the pursuit of free scientific enquiry (ibid, p.67), and any attempt at guiding scientific research towards a purpose other than its own is thus an attempt to deflect it from the advancement of science (ibid, p.62). At the same time, whilst the 'freedom' of the scientist is rooted in scientific tradition, this tradition is such that it allows subversion (ibid, p.69) and thus cultivates 'radical' progression (ibid, p.72). Nevertheless, in agreement with Kuhn, Polanyi acknowledges that well-established or traditional views can lead to an initial reluctance to the acceptance of new ideas when these ideas are subversive of the basic tenets of the sciences involved. Kuhn's view is that as long as these tenets 'retain an element of the arbitrary, the very nature of research ensures that novelty shall not be suppressed for very long' (Kuhn, 1962, p.5). Polanyi's more comprehensive view is that the open and international nature of science ultimately enables even radical new ideas to take root once the supporting evidence is judged to be sound (Polanyi, 1962, p.72).

One last point should perhaps be made before moving on to the main subject matter of this chapter. However logical some philosophers of science might like the processes of discovery and scientific advance to be, as we shall see in the sections and chapters that follow, science is not necessarily like that. Intuition *is* an important part of scientific work, even within the realms of 'normal science'. Thus, whilst there is undoubtedly some truth in each of the views outlined above, it is Polanyi's thoughts that ring true for the present author, and which are therefore discussed further in this thesis.

3.3 The Nature of Knowledge

A problem arises when discussing the nature of knowledge in that there would appear to be no unambiguous definition of the term 'knowledge'. The most common interpretations are therefore outlined and discussed below. Yet, despite their differences, what becomes clear when all of these interpretations are looked at in more detail is that they all point towards the inherently personal nature of the complex 'thing' that is generally referred to as knowledge (Polanyi, 1958, p.vii).

Justified True Belief

Philosophers commonly refer to knowledge as 'justified true belief', a concept that was first introduced by Plato in his *Meno, Phaedo,* and *Theaetetus* (Nonaka and Takeuchi, 1995, p.21). But what does 'justified true belief' really mean? If the belief is in reality true, why does it have to be justified? If, on the other hand, the belief is simply something that is truly believed, then it is simply a belief. Justification in this case may prove the reality of the belief but then that brings in the question, 'Justified by whom and in what way or by what rules?' As will be shown below, what is a justified true belief to one person may not necessarily be a justified true belief to another, since the evidence available to and the interpretation made by one person is not necessarily the same as the evidence available to and the interpretation made by another.

That which is Known

Knowledge is also referred to as 'that which is known' (Quintas and Jones, 1999. p.36). Although true in one respect, it might also be added that we 'know' information. More importantly, this definition begs the question, 'Known by whom?' Since what we know at any one time is likely to be influenced by our past knowledge, experiences, values, and culture, once again, knowledge is not necessarily a universal truth, but is something that is unique to the individual (Brown and Duguid, 1998, p.95; Daft, 1995, p.3; Polanyi and Prosch, 1975, p.44).

Data, Information, Knowledge

Within the general management literature, knowledge is often associated with data as well as information. The story goes: data is a set of unorganized facts or observations; information is data arranged and processed into meaningful patterns; and knowledge is information put into productive use, made actionable, given meaning (Davenport and Prusak, 1998, respectively, pp.2, 3 and 5). This story is often assumed to imply that knowledge is an 'object' or 'commodity' that can be stored, arranged, and otherwise worked upon. However, when looked at in more detail it can be shown that, once again, knowledge is inherently a personal phenomenon.

The word 'data' has its roots in the Latin for 'giving' (*dare* 'to give'; *dator* 'giver'). Data is all around us. It is potentially infinite. It is present, *giving* out a signal to those who are capable of observing it in a meaningful manner. However, we may not necessarily notice

that signal, and, even if we do, it may appear irrelevant for our current purposes. As a consequence, the data that we observe is likely to be that which either informs us (*informare* 'to give shape to') about something or which would appear to have the potential to inform us about something. At any one time, we thus make a judgement as to what data is important to us. The data we observe is therefore inherently personal and context dependent. So what then is information and how does it differ from data?

Information can perhaps best be thought of as pre-selected data that has been processed to provide some meaningful pattern. But can we be sure that the pattern provided is the one that we would ourselves have established? Are we aware of the context for which or within which the data was selected? Are we in fact interpreting the meaningful pattern in the way in which it was intended? Can we even observe the meaningful pattern? What is information to one person has often been observed to be merely data to another. Without the same 'interpretation code' we will not necessarily derive the same meaning from information that others might or have derived from it (Itami, 1992, in Ray and Little, 2001, p.162; Cilliers, 2000, p.10). Information, like data, is thus also inherently personal and context dependent. What is required for information to inform in the way in which it was intended is that the information producer and the information receiver share a common understanding of how the information should be interpreted. So, for information to be made actionable in the way in which it was originally intended, and thus be termed knowledge, not only does the information need to be remembered, but so also must the interpretation code or the common understanding associated with that information. As pointed out by Spradley, language is a tool for constructing reality. And, different languages create and express different realities. They categorize experience in different ways. They provide alternative patterns for customary ways of thinking and perceiving

(Spradley, 1979, p.17). In effect, a common language can be seen as a vehicle for constructing a common understanding. Thus existing knowledge is always context dependent (Tsoukas, 1996, p.11; McKinlay, 2000, p.119) and its effective application is dependent upon the sharing of a common language, whether it is expressed in written, verbal or non-verbal form. Knowledge can thus be defined as information that is remembered in a particular way. Without the common language which conveys the understanding behind the information, it is hard to see how people can communicate and knowledge can be transferred. The result is that whilst information may flow, knowledge will not necessarily do so. In this sense, it is only information that can exist independently and thus be directly acquired, shared, or, in general, transferred.

Within a Western context, 'language' is typically associated with the written or verbal word, and the knowledge resulting from the sharing of such a language is generally referred to as 'explicit knowledge'; it is 'knowledge that can be codified and clearly defined and thus conveyed in written form' (Nonaka and Takeuchi, 1995, p.viii). However, even within a Western context it is recognized that there is some knowledge that cannot be written down or spoken about verbally. As Polanyi has often been quoted as saying: 'I shall consider human knowledge from the fact that *we can know more than we can tell*' (Polanyi, 1966, p.4, italics in original). This is the knowledge of insight and of intuition. It is evidenced by the fact that, for example, the driver of a car can initiate an emergency stop as much as 0.5 seconds before he/she is conscious of perceiving the reason to do so (Ray, 2001, p.4). It is evidenced by the group's spontaneous laughter that breaks out before anyone can say why this should be (Ray, 2005, p.17). This tacit 'knowing' is something that is unknowable in any abstract sense; its existence is only implied by the ability to 'do things' in the course of purposeful activity (Ray and Carter *et al*, 2002, p.20).

A frequently quoted example in the Knowledge Management literature is the act of riding a bicycle. How can we talk or write about the knowledge of riding a bicycle? The answer is that we cannot do so in any meaningful way. We each learn how to ride a bicycle through our attempts at trying to ride a bicycle. And, throughout our attempts we remember and apply the experience we have gained previously to inform our subsequent actions, but we do this without conscious thought of the cognitive processes that make these activities possible. In effect, we gain the knowledge of how to ride a bicycle through practice. Tacit knowledge (as this knowledge is often referred to) 'is preconscious; it cannot be consciously turned off but kicks-in automatically to shape practice' (Ray, 2001, p.4). It is thus quite distinct and wholly different from explicit knowledge.

The practice of R&D involves the sharing of knowledge within and between a number of different departments or organizational functions (technical, operations, marketing, sales, finance, etc.) sometimes external to the company. Thus terms such as 'group knowledge' and 'organizational knowledge' would appear to be appropriate within such a context. Whilst it would seem clear that the presence of a common language that is understood by all members of the 'collective' is necessary for both of these forms of knowledge, previous literature reports would suggest that this has not always been deemed so. For example, Simon saw organizational knowledge as being synonymous with the knowledge of the organization's individual members. New organizational knowledge is then created either by the learning of these members, or by ingesting new members with knowledge the organization did not have previously (Simon, 1991, p.125). In contrast, other researchers have seen organizational knowledge as being something more than simply the sum of the organization's individual knowledge. In particular, Nelson and Winter refer to organizational knowledge as 'an attribute of the firm as a whole, as an organized entity'

which is 'not reducible to what any single individual knows, or even to any simple aggregation of the various competencies and capabilities of all the various individuals, equipment, and installations of the firm' (Nelson and Winter, 1982, p.63). Brown and Duguid try to make this point more clearly and suggest that when individuals have similar backgrounds and experiences – that is they have the same information and speak the same language in all senses of the word 'language' – they can arrive at a shared understanding of what is meant by particular actions or information. This shared understanding is what Brown and Duguid term collective or group knowledge (Brown and Duguid, 1998, p.96). Whilst emphasizing that all knowledge is inherently personal, this is the view that will be taken in this thesis when reference is made to all forms of group knowledge.

A Fluid Mixture of Framed Experience, Information, Values and Insight

To talk about knowledge is perhaps to imply that knowledge (as opposed to knowing) is a static phenomenon. In some instances this may be so: knowledge of the car, for example, might be thought of as essentially static in the sense that cars have standard features (such as an accelerator or drive pedal, brakes, a transmission system and so on) that are arranged in relatively standard design configurations. But, as time passes, the knowledge that we each individually or as a group hold is constantly changing. What we know and how we interpret new information and stimuli is constantly reviewed or revised as we experience and learn new things. One definition that indicates the complex and changing nature of knowledge and indicates that knowledge might in fact be created in the mind of the individual is the one suggested by Davenport and Prusak:

> 'Knowledge is a fluid mix of framed experience, values, contextual information, and expert insight that provides a framework for evaluating and incorporating

new experiences and information. It originates and is applied in the minds of knowers.' (Davenport and Prusak, 1998, p.5)

Michael Polanyi's Tacit Knowing

Although, many contributors to the knowledge debate refer to tacit knowledge and make reference to the historic work of Michael Polanyi, it would appear that few have taken the time to understand what this author is really trying to say. This is a pity, since Polanyi's original ideas offer us a much deeper insight into the nature of knowledge than is presented in much of the contemporary Knowledge Management literature. Whilst the following paragraphs cannot do justice to the wider implications of Polanyi's philosophical insights, they aim at reflecting the logically coherent nature of his propositions. These paragraphs outline how, by using the work of Gestalt psychology and viewing knowledge from the perspective of the individual, Polanyi illustrates how all human action is based upon tacit thought, and, as a consequence, all knowledge, even that which is commonly referred to as being explicit, includes a tacit dimension.

As mentioned above (page 95), Polanyi began his investigation into 'The Tacit Dimension' by considering human knowledge from the fact that '*we can know more than we can tell*' (Polanyi, 1966, p.4, italics in original). That is, there is more to knowledge than that which can be expressed in explicit terms. He gives, as an example of this fact, the way that teaching occurs in the descriptive sciences. He notes that all descriptive sciences study physiognomies that 'cannot be fully described in words, nor even by pictures.' However, the possibility that these physiognomies can be learnt through practical exercises suggests that nevertheless 'we can tell our knowledge of them'. But, as he points out, we can do

this only by 'relying on the pupil's intelligent co-operation for catching the meaning of the demonstration' (Polanyi, 1966, p.5). Polanyi refers to this knowledge that cannot be told as '*tacit knowing*'. He notes that Gestalt psychology has demonstrated that we may know a physiognomy by integrating our awareness of the particulars of this physiognomy without being able to identify these particulars. And he takes the view that the 'shaping and integrating' that occurs, is the 'great and indispensable tacit power by which all knowledge is discovered and, once discovered, is held to be true' (ibid, p6). From this background, he develops a structure for tacit knowing and explains how we each exercise our tacit powers of knowing.

In Polanyi's view, the structure of tacit knowing consists of two components (viz. Polanyi's 'terms'): the *proximal* and the *distal*. The former can be associated with the particulars of tacit knowing, the latter with the focal target of the act of tacit knowing (Polanyi and Prosch, 1975, p.34). Polanyi adds that it is the proximal component 'of which we have knowledge that we may not be able to tell' (Polanyi, 1966, p.10). He arrives at this conclusion by referring to the electric shock experiments of McCleary and Lazarus (1949) and Eriksen and Kuethe (1956). In McCleary and Lazarus' experiments a subject was shocked after being shown certain nonsense syllables, and learnt to expect the shock event (McCleary and Lazarus, 1949, p.178). In Eriksen and Kuethe's experiments, a subject learnt to suppress the utterance of certain word associations which would evoke the shock (Eriksen and Kuethe, 1956, p.207). In both cases the shock-producing particulars (the proximal component) remained tacit: the subject could not identify them. However, the subject did learn to connect the shock-producing particulars with the electric shock (the distal component) that subsequently occurred. When this was so, the sight of the shock

syllables led to the expectation of a shock, and the utterance of the shock associations was suppressed in order to avoid the shock.

In considering why the connection remained tacit, Polanyi concludes that it was because the subject was 'riveting his attention on the electric shock' and was 'relying on his awareness of the shock producing particulars only in their bearing on the electric shock' (Polanyi, 1966, p.9). In general, he suggests that we know the proximal component only by relying on our awareness of it for attending to the distal component. In the act of tacit knowing, we therefore 'attend *from* something for attending *to* something else' (ibid, p. 9, italics in original). Polanyi calls this *from-to* relationship the functional relation between the two components of tacit knowing. The components together with their relationship form the functional structure of tacit knowing (ibid, p.10).

Polanyi then adds that although the subjects of the experiments cannot explicitly identify the shock-producing particulars, they do become aware of them in terms of the apprehension they invoke. Thus, he says, 'we are aware of the proximal term of an act of tacit knowing in the appearance of its distal form; we are aware of that *from* which we are attending *to* another thing, in the *appearance* of that thing.' He calls this the phenomenal structure of tacit knowing (ibid, p.11, italics in original).

Furthermore, once the connection is made, the shock-producing particulars can be said to *signify* the approach of a shock. This is the meaning of the shock-producing particulars to the subject. In general, 'when the proximal component of an act of tacit knowing arouses an apprehension in us, without our being able to identify that component itself, we can say that we know this component only in terms of its *meaning*' (ibid, p.11). In this sense,

meaning can be said to be displaced away from the subject – hence Polanyi's justification of the terms proximal and distal. This is the semantic aspect of tacit knowing (Polanyi, 1966, p.13).

Polanyi suggests that there is a fourth aspect of tacit knowing which can be deduced from the functional, phenomenal and semantic aspects. His argument is that since tacit knowing establishes a meaningful relation between two terms, it can be identified with an '*understanding* of the comprehensive entity which these two terms jointly constitute'. This is the ontological aspect, which tells us what tacit knowing is a knowledge of. In Polanyi's terminology, 'we comprehend the entity by relying on our awareness of its particulars for attending their joint meaning' (ibid, p.13).

Polanyi then suggests that when we make a thing function as the proximal component of tacit knowing we 'incorporate it into our body, or extend our body to include it, so that we come to dwell in it' (ibid, p.16). He adds that it is by dwelling in the proximal component, whilst focusing on the distal component that we can, for example, understand a work of art, understand the mind of another person, and apply a theory within the practice of science (ibid, p.17). As he says, 'It is not by looking at things, but by dwelling in them, that we understand their joint meaning' (ibid, p.18).

3.4 The Knowledge Creation Models

3.4.1 Michael Gibbons and Co-workers' Modes of Knowledge Production

Traditionally, knowledge was produced within a disciplinary context. Schools and universities taught knowledge from a disciplinary perspective (physics, chemistry, mathematics, social science, etc.) and industrial organizations separated their activities into discipline-based functional departments (chemistry, finance, human resources, etc.). Thus, it was the discipline that determined the cognitive and social norms which had to be followed in the production, legitimization and diffusion of knowledge (Gibbons *et al,* 1994, p.1). Forms of practice which adhered to the rules of the discipline were then termed 'scientific' whilst those that violated them were not 'scientific'. Mode 1 knowledge production is thus often referred to as 'scientific' knowledge production. Gibbons *et al* define it as:

> 'The complex of ideas, methods, values and norms that has grown up to control the diffusion of the Newtonian model of science to more and more fields of enquiry and ensure its compliance with what is considered sound scientific practice' (Gibbons *et al*, 1994, p.167).

Mode 1 knowledge production assumes a linear view of science and innovation: to discover new ideas, transfer them, and then exploit them in new products (ibid, p.60). It assumes a separation of producers and consumers of knowledge. It carries a distinction between what is fundamental and what is applied (ibid, p.19). Quality is determined mainly through peer review judgements about the contributions made by individuals. And, control is maintained by careful selection of those judged competent to act as peers, which is in part determined by their previous contributions to their disciplines. It is thus a process

in which quality and control mutually reinforce one another. Mode 1 is clearly the primary form of knowledge production in first generation (science/technology push) R&D (Chapter 2, Section 2.2.1, page 18).

However, Gibbons *et al* contend that there is sufficient empirical evidence to indicate that a distinct set of cognitive and social practices is emerging which differs from that which governs Mode 1 knowledge production. And, these cognitive and social practices are emerging from knowledge generation carried out for the purpose of achieving a practical goal. They define this new form of knowledge production as:

> 'Knowledge production carried out in the *context of application* and marked by its: *transdisciplinarity; heterogeneity*; organisational heterarchy and transience; social accountability and *reflexivity*; and quality control which emphasises context- and use- dependence' (Gibbons *et al*, 1994, p.167, italics in original).

Mode 2 knowledge production is transdisciplinary in that 'consensus is conditioned by the context of application and evolves with it': the final solution does not arise solely, or even mainly, from the application of knowledge that already exists; is normally beyond that of any single contributing discipline; cannot necessarily be reduced to disciplinary parts; and is developed using its own distinct theoretical structures, research methods and modes of practice, which are not necessarily located on the prevailing disciplinary map (Gibbons *et al,* 1994, p.4). Mode 2 knowledge production is heterogeneous in terms of the skills and experience people bring to it, with the composition of the problem solving team changing over time as requirements evolve, rather than being planned or coordinated by any central body. Mode 2 knowledge production involves organizational heterarchy and transience in that people from diverse backgrounds and from different locations or organizations come together in temporary work teams and networks, which dissolve when a problem is solved or redefined (ibid, p.6). And, social accountability and reflexivity to the impact of research

is built-in to Mode 2 working in that research teams involve social scientists working alongside natural scientists, engineers, lawyers and business people (Gibbons *et al,* 1994, p.7). In consequence, quality is determined by criteria that reflect both the context of the application and the standpoints of the participants involved (ibid, p.8).

Unlike Mode 1 knowledge production 'where results are communicated through institutional channels, the results [of Mode 2 working] are communicated to those who have participated in the course of that participation'. Subsequent diffusion of the resulting knowledge then occurs primarily as the original practitioners move to new problem contexts. A particular solution can become the cognitive site from which further advances can be made, but it is difficult to predict where this knowledge will be used next and how it will develop (ibid, 1994, p.4). In Mode 2 working, 'science and innovation' is therefore no longer a linear process: ideas arise throughout the problem solving process; there is no distinct separation between producers and consumers; and there is no distinction between what is fundamental and what is applied, or between what is theoretical and what is applied science. Discovery and application cannot be separated, since the relevant science is produced in the course of providing solutions to problems defined in the context of application (ibid, p.33). Hence, Mode 2 knowledge production would appear to be most closely related to the third, fourth, and fifth generations of R&D (Chapter 2, Sections 2.2.3, 2.2.4, and 2.2.5, respectively, pages 23, 25, and 29).

Although Gibbons *et al* see no need for Mode 2 activities to be institutionalized in a particular way, or for participants to move permanently to new institutional locations, they do see other implications for all institutions engaged in knowledge production, whether they are universities, government research establishments, or corporate laboratories.

First, because of its *modus operandi*, Mode 2 knowledge is both supplied by and distributed to individuals and groups across the social spectrum. The degree to which knowledge producing institutions become more permeable will not, according to Gibbons *et al,* alter the fact that knowledge production is becoming more widely distributed. Hence, institutions unprepared to become permeable may well end up being scientifically and technically isolated from some intellectual developments (Gibbons *et al*, 1994, p.14).

Second, since Mode 2 knowledge is context specific, much [one might say all] of the transferable knowledge resulting from this mode of knowledge production is tacit knowledge embodied in the people participating in the process. This is expected to have a fundamental influence on how institutions design and organize their knowledge producing activities in the future (ibid, p.18). One implication that Gibbons *et al* foresee is that there will be closer integration of the process of discovery with that of fabrication (ibid, p.19). Another is that the organization of research will be more open and flexible (ibid, p.20).

Third, in Mode 2 knowledge production, preference is given to collaborative rather than individual performance, and excellence is judged by the ability of individuals to make a sustained contribution in open, flexible types of organization in which they may only work temporarily (ibid, p.30). Since resources are often held in different organizations, organizational boundaries become blurred. As a consequence, these resources may be at one moment collaborative and at another competitive (ibid, p.48).

Fourth, the expansion in the number, nature and range of communicative interactions between different sites of knowledge production will lead not only to more knowledge being produced but also to more knowledge of different kinds (ibid, p.35). Gibbons *et al*

note that numerous novel pathways towards solutions can be traced to encounters between scientists brought together from different sites, and they suggest that the more mobility a science system permits or even encourages, the more potential instances of this kind can be expected (Gibbons *et al,* 1994, p.36).

Fifth, they suggest that the transient research clusters of Mode 2 will increasingly produce the specialist knowledge that will come to characterize the knowledge industries of the future (ibid, p.69).

It is perhaps no coincidence that the emergence of Mode 2 (or perhaps more accurately its increase) occurred as Western governments (a) reduced their overall funding to universities and (b) placed a greater emphasis on the funding of research for economic purposes. Rather than continuing to carry out fundamental research, universities were encouraged, if not forced, to enter into a range of collaborative ventures with industry and pursue research within the context of application. Arguably, there are clear advantages: knowledge *is* more widely distributed, university researchers can widen their horizons, and it is always satisfying to see the results of one's efforts being used. But at the same time, one might question the loss of interest in the basics of science inherent in Mode 1 working.

Gibbons *et al* argue that parallel to the diffusion of Mode 2 knowledge production, network firms, R&D alliances, high value-added firms and new interface relations between competition and collaboration will emerge. They suggest that firms will take on some of the characteristics of a spider's web, whereby each node in the web is a problem-solving team possessing a unique combination of skills, which is linked to other nodes by a potentially large number of lines of communication (ibid, p.122), and whereby the nature

and viability of nodes is intertwined with changing circumstances. In consequence, flows of knowledge, products, people and ideas become more important than structures (Gibbons *et al,* 1994, p.138). The source of value-added will then lie in the precise form which the collaboration of groups and the experience and skills of its members take (ibid, p.112). That is, the locus of value-added shifts from the creation of knowledge to its configuration (ibid, p.122).

Finally, Gibbons *et al* point out that the interdependence of research and industrial innovation implies a degree of vulnerability for those engaged in research and with this in mind, they pose three questions:

> 'How much stability, predictability and routine is needed to support the more exotic, intermittent and transitory unstable patterns of transdisciplinary work? How much fungibility[10] is possible? How much insecurity can individual researchers bear without their creativity suffering?' (Gibbons *et al*, 1994, p.150)

They suggest that adaptability is the condition for continued success, and that an environment is needed which cultivates institutional openness and flexibility and which allows room for experimentation and initiative in local arrangements (ibid, p.150).

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[10] Fungibility was not defined, but was said to increase when scientists or engineers are moved to new jobs, demanding other skills and a different knowledge profile (Gibbons *et al,* 1994, p.150).

3.4.2 Organizational Knowledge Creation according to Ikujiro Nonaka and Hirotaka Takeuchi

Nonaka and Takeuchi describe organizational knowledge creation as a spiral process (Nonaka and Takeuchi, 1995, p.57). They assume that knowledge is created within the mind of the individual, but is then converted into higher level knowledge (group, organizational, inter-organizational) through four knowledge conversion processes: socialization, externalization, combination, and internalization (ibid, p.62). They link these knowledge conversion processes with four modes of interaction involving tacit knowledge and/or explicit knowledge (ibid, p.61).[11] Their overall process is shown diagrammatically in Figure 3.3.1 (next page).

Socialization is the conversion of tacit knowledge to new tacit knowledge. It comes about through the sharing of experiences, and is the way in which mental models and skills are shared as, for example, when the apprentice learns craftsmanship through observation, imitation, and practice (ibid, p.62). The knowledge created is termed 'sympathized' knowledge (ibid, p.71). Externalization is the conversion of tacit knowledge to explicit knowledge, which is achieved by the use of metaphors, analogies, concepts, hypotheses, or models (ibid, p.64). The knowledge created is termed 'conceptual' knowledge (ibid, p.71). Combination is the conversion of explicit knowledge to yield new explicit knowledge by the combination and reconfiguration of different bodies of explicit knowledge, as held in, for example, documents, meetings, telephone conversations, or computerized communication networks. Prototypes or combined component technologies are given as examples (ibid, p.67). The knowledge created is termed 'systemic' knowledge (ibid, p.71).

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[11] Tacit knowledge and explicit knowledge are here assumed to be as described in Section 3.3, page 95.

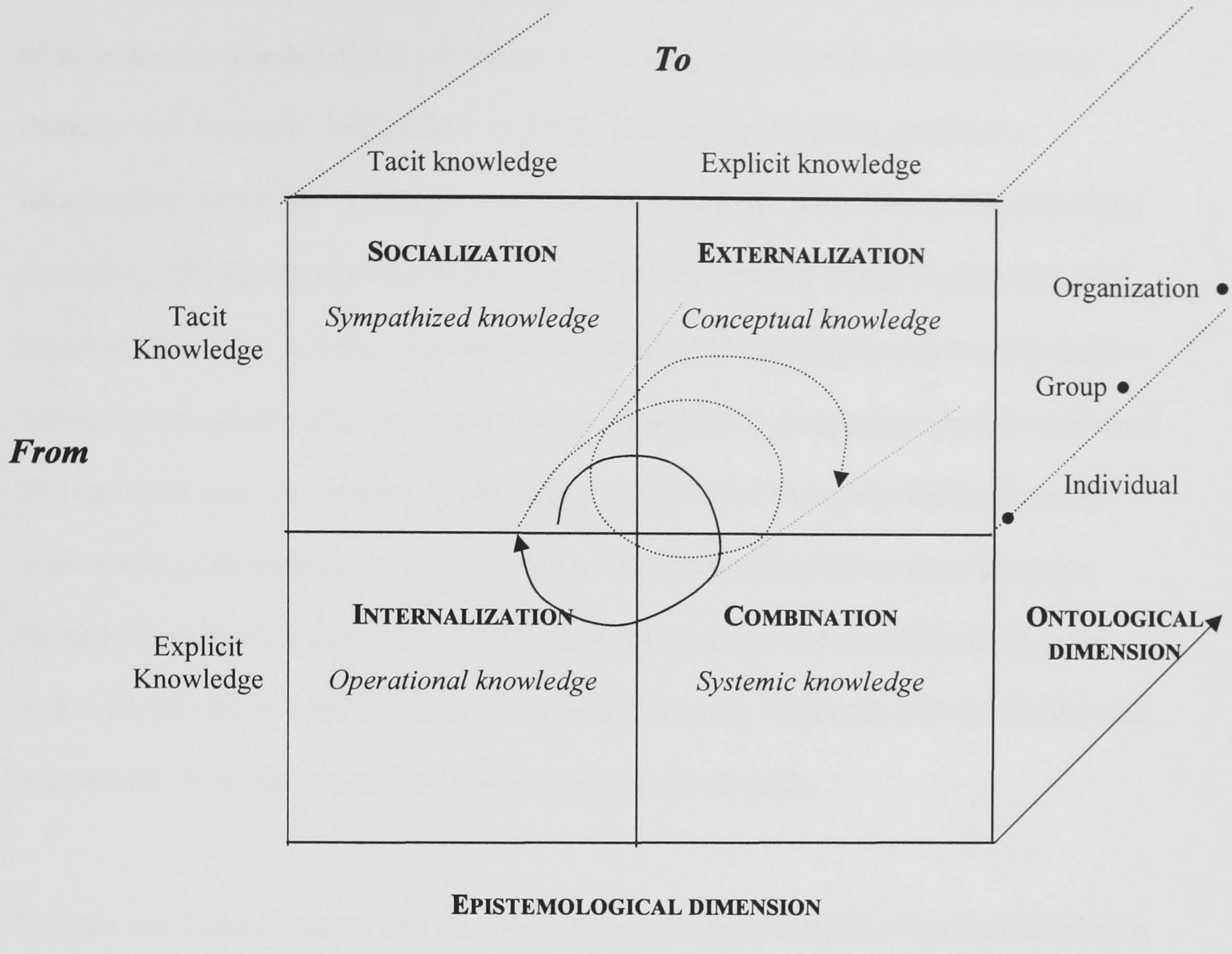

FIGURE 3.3.1: THE ORGANIZATIONAL KNOWLEDGE CREATION SPIRAL
Adapted from Nonaka and Takeuchi, 1995: Figure 3.2, p.62; Figure 3.3, p.71; and Figure 3.5, p.73

Internalization is the conversion of explicit knowledge to tacit knowledge. It is the process of embodying explicit knowledge into the tacit knowledge of the individual, the group, or the organization (Nonaka and Takeuchi, 1995, p.69). The knowledge embodied typically includes knowledge about project management, production processes, new product usage, and policy implementation. The knowledge created is termed 'operational' knowledge (ibid, p.71).

Based upon their knowledge conversion process, Nonaka and Takeuchi suggest that new product development is a five-phase process that involves the sharing of tacit knowledge

(socialization), the creation of and justification of concepts (externalization), the building of an archetype (combination), and the cross-levelling of knowledge (internalization) (Nonaka and Takeuchi, 1995, p.83). And they identify five enabling conditions: organizational intention – the organization's aspiration to its goals (ibid, p.74); individual autonomy – the acceptance that all members of an organization should be allowed to act autonomously as far as circumstances permit (ibid, p.75); fluctuation and creative chaos – internally and intentionally generated fluctuation and chaos designed to improve reflection, and focus attention on problem definition and resolution of an appropriately generated crisis (ibid, p.79); redundancy of information – the existence of information that goes beyond the immediate operational requirements of organizational members (ibid, p.80); and requisite variety – the organization's internal diversity is a match with the variety and complexity of the environment in which it operates (ibid, p.82).

Nonaka and Takeuchi argue that Japanese companies are successful at innovation because they are particularly good at systematic organizational knowledge creation (ibid, p.17). And this, they imply, is largely because, unlike their Western counterparts, they have effective group-based processes (ibid, p.198).

Nonaka and Takeuchi's work has been the basis for a number of subsequent studies in the Knowledge Management literature (Armbrecht *et al*, 2001, p.46; Becerra-Fernandez and Sabherwal, 2001, p.25). However, their work has been criticized on several counts.

First, McAdam and McCreedy suggest that knowledge transfer in organizations is more complicated and convoluted than Nonaka and Takeuchi's simple cycle of socialization,

externalization, combination and internalization implies (McAdam and McCreedy, 1999, p.91).

Second, Ray and Carter *et al* point out, that Nonaka and Takeuchi do not remain entirely true to Polanyi's original definition of tacit knowledge. Nonaka and Takeuchi refer to 'tacit' knowledge as being something that is not *easily* visible and expressible, and which is thus *difficult to* communicate to or share with others. They separate 'tacit' knowledge into two dimensions: the first is the 'hard-to-pin-down' skills or crafts captured in the term 'know-how'; the second consists of 'ingrained schemata, mental models, beliefs and perceptions that reflect our image of reality (what is) and our vision for the future (what ought to be) that shape the way we see the world around us' (Nonaka and Takeuchi, 1995, p.8). It is conceivable that with such a definition, some tacit knowledge might well be expressible as explicit knowledge. However, importantly, the proposal that 'tacit knowledge is something that cannot be articulated very *easily*' conflicts with Polanyi's view that tacit knowledge *cannot be expressed* at all (Ray and Carter *et al*, 2002, p.20).

Third, Ray and Little point out that Nonaka and Takeuchi's spiral process 'posits an ontological continuum from the individual to the wider community, the implication being that different types of knowledge can be converted into a common currency and moved from one context to another'. However, this begs the question: 'But what about the "interpretation code" (Itami, 1992) that renders information comprehensible and meaningful *in a particular context*?' (Ray and Little, 2001, p.162, italics in original).

Fourth, Ray and Little also suggest that Nonaka and Takeuchi's spiral metaphor 'does not engage with Japan's wider institutional context':

> 'But Nonaka and Takeuchi's spiral metaphor ... [appears] to assume away (1) the role that Japan's institutional framework plays in situating knowledge-generating practice inside Japan's workplace *ba*[12], and (2) the possibility that (through a complex dialectical process) groups influence the personal knowledge created by their members.' (Ray and Little, 2001, p.162)

But what do Nonaka and Takeuchi really mean when they refer to inter-organizational processes? Are they perhaps referring to the links between members of a particular *keiretsu*[13] grouping? Are they perhaps arguing the case for greater collaboration, rather than saying that this collaboration exists? Certainly by talking about a spiral process Nonaka and Takeuchi give the impression that group influence on individual knowledge is not important. However, they do also suggest that the various ontological levels 'are not independent of each other, but interact with each other iteratively and continuously' (Nonaka and Takeuchi, 1995, p.89). Might this not imply that groups do influence the personal knowledge created by their members?

Although the ontological status of groups remains controversial, Cook and Brown (1999) have argued that it is a mistake to reduce the knowledge possessed by a group to the sum of the knowledge possessed by each individual member. The whole is not only greater than the sum of its parts, but also qualitatively different from any given part. Nevertheless, as is outlined in the next section, Cook and Brown argue that group-knowledge and individual-knowledge mutually enable the active process of knowing how to do things in

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[12] *Ba:* Ray and Little explain: 'Although the Chinese character representing '*ba*' roughly means 'place', the concept of *ba* is concerned with the interaction space (which may be real, virtual or a mixture of the two) within which purposeful activity is situated' (Ray and Little, 2001, p.157). Ray and Carter *et al* comment further: 'Itami [1992] has conceptualised *ba* in terms of a bounded context, where those with a willingness to co-operate and a common agenda, interact on a regular basis. In the process, they evolve a shared 'interpretation code' that gives meaning to information signals (which might include gestures, tone of voice or indeed the absence of any signals)'. (Ray and Carter *et al,* 2002, p.16)

[13] Keiretsu: 'A bank-based group of companies bound together through cross-shareholdings, interlocking directorates, intra-group trade, and periodic meetings of member company presidents.' (Ray and Carter *et al,* 2002, p.10)

practice. By combining representations of 'knowledge as a thing' with 'knowing as a process', Cook and Brown thus claim to bridge the divide between abstract knowledge and practical knowing.

3.4.3 Knowledge Generation according to Scott D. N. Cook and John Seely Brown

Cook and Brown propose three shifts that they believe answer some of the criticisms made about Nonaka and Takeuchi's work, namely:

1. It is not possible, under any circumstances, for tacit knowledge to become explicit knowledge (or vice versa), but it is possible for one to be a useful tool for generation of the other through a process of productive enquiry.
2. Since explicit knowledge and tacit knowledge are generated and disseminated each in their own right, whether either can 'be easily leveraged by the organization as a whole' depends on the specific needs and resources that an organization has at hand in a given situation.
3. The production of new knowledge does not lie in a continuous interaction between tacit knowledge and explicit knowledge but rather lies in the use of knowledge as a tool of a productive enquiry as part of a dynamic interaction with the things of the social and physical world (Cook and Brown, 1999, p.397).

Thus, the four categories of knowledge assumed in Nonaka and Takeuchi's model are now seen as distinct and co-equal forms. They constitute 'what is known'. They are the

knowledge that people or groups possess, and thus provide the appropriate focus for an 'epistemology of possession' (Cook and Brown, 1999, p.382).

Specifically, Cook and Brown argue that knowledge (as possession) is static. One form of knowledge cannot be made out of or converted into the other, but each form of knowledge may be used as an aid in acquiring the other:

> 'If you know how to ride [a bicycle], for example, you might use your tacit knowledge to ride around in a way that helps you discover which way you turn when you begin to fall. Likewise, if a novice is told how to turn to avoid a fall, that explicit knowledge could be used while learning to ride as an aid in getting a feel for staying upright.' (Cook and Brown, 1999, p.385)

Similarly:

> 'While individual copier technicians have a sense of how a particular copier ought to sound when operating properly (groups do not have ears), it is a group of technicians that possess "war stories" about what odd noises can mean … part of what is known about a given domain is possessed by individuals, part by groups … The "body of knowledge" of a group is "held in common" by the group. We do not expect every individual in a group (discipline, profession, craft, etc.) to possess everything that is in the 'body of knowledge' of that group.' (Cook and Brown, 1999, p.386)

Furthermore, Cook and Brown contend that there is more in what we know 'how to do' than can be accounted for solely in terms of the knowledge we possess (ibid, p.382). For example, they claim that the act of riding a bicycle does distinct *epistemic* work of its own. And, they hold that this type of epistemic work is an inextricable facet of human action itself. They mark this distinction by referring to it as 'knowing' rather than knowledge, and they introduce an 'epistemology of practice' which takes 'ways of knowing' as its focus (ibid, p.383).

Cook and Brown then make the point that no one form of knowledge can be used by itself to acquire the other, but one must also, at the very least, undertake some activity to enable this to be so (Cook and Brown, 1999, p.385). For example:

> 'Neither tacit nor explicit knowledge can be used by itself to acquire the other: one must also, at the very least, get on a bicycle.' (Cook and Brown, 1999, p.385)

In consequence, an understanding of individual and group action requires consideration of both 'knowledge used in action' and 'knowing as part of action'. In particular, it is the interplay between knowledge and knowing or the 'generative dance' between knowledge and knowing that has the potential to create new knowledge and new knowing (ibid, p.381). By bridging the epistemologies of possession and practice, Cook and Brown suggest that it is possible to draw upon the four forms of knowledge within the same activity. Cook and Brown's Figure 4, presented here in modified form in Figure 3.3.2 (next page), shows the four forms of 'knowledge' with a circle superimposed to represent 'knowing'. The arrows suggest the 'active use of knowledge in our interaction with the social and physical world' (ibid, p.393).

Cook and Brown's view that one form of knowledge can be used as an aid in acquiring another form of knowledge but cannot be converted into another form would appear to be profoundly different to that of Nonaka and Takeuchi's proposal that one form of knowledge is converted into another form. But is the difference as wide as it might seem? Nonaka and Takeuchi talk about knowledge conversion, but what do they really mean by the word 'conversion'? When applying their model to new product development, might not Nonaka and Takeuchi be *implying* the use of one form of knowledge to acquire another form of knowledge, rather than the exact conversion of one form of knowledge into another?

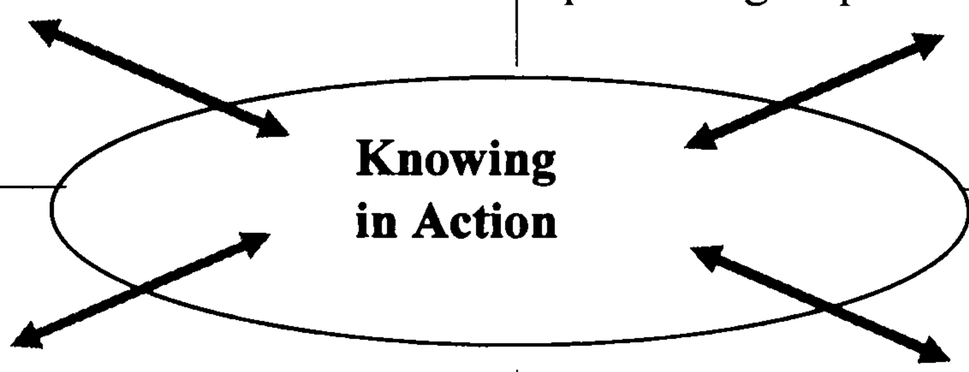
	Individual knowledge	**Group knowledge**
Explicit knowledge	Things an individual can know, learn and express explicitly, e.g.: concepts, rules, equations	Things that are expressed explicitly, yet are typically used, expressed or transferred in a group, e.g.: 'war stories', use of metaphors or phrases that have useful meaning within a specified group
		
Tacit knowledge	Tacit knowledge possessed by individuals, e.g.: a skill in making use of concepts, rules, equations; a 'feel' for the proper use of a tool or for keeping upright on a bicycle	Tacit knowledge possessed by groups, which covers the distinctive and useful meanings a given group attaches to its various literary, physical and social artefacts, and its different types of activities (termed organizational genre). Meanings emerge and undergo constant confirmation and/or modification through a kind of 'negotiation in practice' as they are used in the context of the group's ongoing work

FIGURE 3.3.2: A PLURALIST FRAMEWORK OF KNOWLEDGE AND KNOWING
Source Cook and Brown, 1999, Figure 4: Adding Knowing to Knowledge, p.391

3.4.4 Knowledge Creation according to Michael Polanyi

In Section 3.3, we saw how Polanyi defined tacit knowing. We also saw that when we make a thing function as the proximal component of tacit knowing we 'incorporate it into our body' and 'dwell in' it, and by indwelling in the proximal component whilst focusing on the distal component we arrive at an understanding of their joint meaning. This section expands upon Section 3.3 and describes how Polanyi takes his argument further and explains how we each create our own personal knowledge.

Polanyi suggests that the way in which we come to understand (and learn from) each other is through the use of two kinds of indwelling. He gives, as an example, the way in which one person comes to understand the skilful performance of another. Whilst the performer co-ordinates his moves by dwelling in them as part of his body, the watcher tries to correlate these moves from outside. By exploratory indwelling, the watcher eventually comes to *interiorize* these moves within his/her body. The performer skilfully uses his/her body; the watcher 'cleverly' uses his/her mind. Polanyi then suggests that similar situations hold when one person tries to understand the mind of another, as chess players seek to do by rehearsing the games of the chess master (Polanyi, 1966, p.30) and, it might be added, as scientists seek to do by repeating the work of others. As Polanyi notes, 'the question of how we can infer the existence of other minds from observing their external workings does not arise, for we never do observe these workings in themselves.' Instead, it is a case of 'picking out clues with a personal bearing on the presence of something they appear to indicate' (ibid, p.31). By extension, by exploratory indwelling in the particulars of the information available to us, we are able to arrive at the meaning of these particulars in the context within which we are operating.

Polanyi argues that throughout the course of our lives we keep expanding our body into the world, by assimilating to it sets of particulars which we integrate into reasonable entities. By exercising our tacit powers of knowing, we 'form intellectually and practically, an interpreted universe populated by entities, the particulars of which we have interiorized for the sake of comprehending their meaning' (Polanyi, 1966, p.29).

Polanyi believes that the two components of tacit knowing – the proximal which involves the particulars and the distal upon which we focus – can be viewed as two levels of reality, controlled by distinctly different principles. But, he notes that 'between two such levels a logical relation exists, which corresponds to the fact that the two levels are the two terms [components] of an act of tacit knowing which jointly comprehends them' (ibid, p.34). Polanyi pictures the universe as consisting of strata of realities, joined together meaningfully in pairs of higher and lower strata' (ibid, p.35).

Because the laws governing the different levels of reality are distinct, one from the other, Polanyi suggests that a higher level can come into existence only through a process not manifest in the lower level, a process which thus qualifies as *emergence* (ibid, p.45). And it is through the particular process of emergence that results from the combination of tacit comprehension with a set of fixed logical operations that a child first learns to comprehend the world and, in later life, the adult learns to deepen his/her understanding. Hence, through emergence, new knowledge is formed or created:

> 'A child starts off with a scanty repertoire of innate mental connections and enriches them rapidly by using his powers of comprehension for establishing further fixed relations of experience … Stimulated by the interiorization of language, this development eventually produces the adult mind. (Polanyi, 1966, p.45)

Polanyi's view of knowledge suggests that tacit thought forms an indispensable part of all knowledge. That is, even the knowledge that is often referred to as 'explicit' has a tacit dimension, since it is formed through our own actions of tacit knowing (Polanyi, 1969, p.195; Polanyi and Prosch, 1975, p.91). By indwelling in the particulars, we arrive at a comprehension of the thing we are trying to understand – an act of tacit knowing. We may think that we can make, to some extent, the knowledge so formed explicit, but in so doing we will of necessity be imparting our own original tacit assumptions. In addition, the transfer of any knowledge to another person, whether or not we can make that knowledge explicit, will depend upon the other person's 'intelligent co-operation for catching the meaning of what we are saying or demonstrating' – another act of tacit knowing. And, since it might be expected that we are all of us unique in the strata of realities that we hold, it may well be that the understanding so obtained may differ from ours. Thus, again, the knowledge that we each hold is inherently personal to ourselves.

The above points have important implications for the organizational knowledge creation models of Nonaka and Takeuchi and Cook and Brown reported above. First, if all knowledge includes a tacit dimension, can we really accept the tacit-explicit split suggested in these models. Second, if all knowledge is indeed personal can we really adopt the concept of group knowledge also advocated within these models? Whilst we might be able to accept that there is some knowledge that is personal to the group, can we really be sure that such knowledge is held in the same way by all members of the group? Or does this really matter? Third, the need for indwelling suggests that organizational knowledge creation is neither the simple knowledge conversion process proposed by Nonaka and Takeuchi nor the 'generative dance' between knowledge and knowing proposed by Cook and Brown.

Polanyi's thoughts are additionally important in that they provide greater insight into the personal act of discovery. Polanyi points out that 'it is commonplace that all research must start with a problem'. And so he asks the question, 'But how can one see a problem?' He points out that to see a problem is to see something that is hidden; to have an intimation of the coherence of hitherto not comprehended particulars (Polanyi, 1966, p.21). He adds that we take this for granted without noticing the clash of self-contradiction entailed. He notes that Plato has pointed out this contradiction in the *Meno*.

> 'He [Plato] says that to search for the solution of a problem is an absurdity; for either you know what you are looking for, and then there is no problem; or you do not know what you are looking for, and then you cannot expect to find anything.' (Polanyi, 1966, p.22)

Whilst Plato offers the solution that all discovery is a remembering of past lives (past experiences?), Polanyi concludes that the resolution of the paradox of the *Meno* lies in the tacit knowledge that we each possess (ibid, p.22); tacit knowledge that yields an intimation of something hidden which we may yet discover (ibid, p.23). In the pursuit of discovery, 'all the time we are guided by sensing the presence of a hidden reality toward which our clues are pointing; and the discovery which terminates and satisfies this pursuit is still sustained by the same vision. It claims to have made contact with reality: a reality which, being real, may yet reveal itself to future eyes in an indefinite range of unexpected manifestations.' (ibid, p.24). In essence, the pursuit of discovery is based upon an insight into what might be; an insight which is 'simply our own meaningful integration of the parts of the complex entity' we are trying to understand (Polanyi and Prosch, 1975, p.54).

Thus, as Polanyi points out, tacit knowing can account for a valid knowledge of a problem; for the scientist's capacity to pursue it, guided by his/her sense of approaching its solution: and for a valid anticipation of the yet indeterminate implications of the discovery arrived at

(Polanyi, 1966, p.24). Hence, discovery involves a deep commitment that something is there to be discovered that will offer a deeper understanding of reality; that it is personal, in the sense that it involves the personality of the scientist so committed; and that it involves a personal judgement in relating evidence to an external reality. Polanyi concludes, 'The anticipation of discovery, like discovery itself, may turn out to be a delusion. But it is futile to seek for strictly impersonal criteria for its validity' (ibid, p.25). Thus, we might conclude, even scientific discovery cannot be guaranteed to be an 'absolute truth' since it is based in all instances on a reality that is inherently personal.

3.5 Conclusion to the Chapter

After undertaking a brief discursion into the philosophical debate concerning the growth of scientific knowledge in general, this chapter looked at the more recent models of organizational knowledge creation in an attempt to understand how they might apply in the practice of corporate R&D. We have seen that, although Nonaka and Takeuchi's work suggests a model of knowledge creation that is far too ordered to reflect the actual practice of R&D, it does nevertheless hint at the importance of processes such as knowledge sharing (socialization), concept generation (externalization), knowledge combination (combination), and knowledge acquisition (internalization) to that practice. In addition, whilst Cook and Brown's model reflects the intuitive feeling that we use the knowledge, of whatever type, that is available to us at the time to create new knowledge, it gives us little idea of which forms of knowledge and knowing are involved within any particular context, at any particular time, or for any particular purpose. However, more importantly, we have seen how Polanyi's thoughts on the nature of knowledge have implications for not only how knowledge is created by the individual, but how knowledge might be created in organizations.

A general acceptance of the existence of tacit knowledge and explicit knowledge of the individual and group varieties has enabled Nonaka and Takeuchi and Cook and Brown to base their models on the idea that it is meaningful and useful to talk about tacit knowledge and explicit knowledge as if they were identifiable entities. Indeed, Cook and Brown claim that knowledge (whether tacit or explicit) is '*about* but not *in* the tangible world' (Cook and Brown, 1999, p. 387, italics in the original). Yet, if Cook and Brown's four types of knowledge tools (tacit knowledge and explicit knowledge, each possessed by

individuals and groups) are not *in* the tangible world, we might reasonably ask where these four types of knowledge reside? Is it necessary to imagine an *intangible world* to anchor the abstract side of Cook and Brown's epistemological bridge? Polanyi's response to the problem of conceptualizing abstract knowledge was to insist that knowledge is in the heads of persons: it is personal – all of knowledge is tacit or rooted in the tacit dimension and there is no such thing as a strictly independent explicit knowledge.

We have also seen that by investigating the context within which knowledge is created Gibbons and his co-workers have identified a new form of knowledge production – knowledge production in the context of application – which bears some similarities with the later R&D Generations models outlined in Chapter 2. This work, in particular, points to the increasing importance in the West of the social implications associated with the advancement and application of science and technology, and hence towards the need for knowledge production that is conditioned by and evolves with those needs. This would seem to cast doubt on the relevance of corporate research (as opposed to corporate development), since knowledge creation in the context of application would appear to leave little time for scientific discovery, relying instead on the adaptation or exploitation of existing scientific and technical knowledge. One might question whether this will eventually be good for society, since from whence will come the new scientific breakthroughs that can change the way we advance and explore the world? Will they be expected to be the sole province of the universities, many of whom are themselves, because of budgetary pressures, being pushed to work within a context of application?

Chapter 2 has shown us that knowledge creation within Western environments has become increasingly dependent upon knowledge held external to the firm. As a consequence, the

quest for efficient and effective processes for knowledge acquisition and knowledge sharing, and for the subsequent application of that acquired and shared knowledge have become important objectives within Western R&D. However, since knowledge acquisition and knowledge sharing are not the simple processes that they are often assumed to be, we might question such an approach. This and related issues raised in this present chapter will be discussed further in Chapter 6. In the meantime, Chapter 4 outlines the methodology used in the empirical research conducted for this thesis, and Chapter 5 presents the findings of that research.

4 METHODOLOGY

4.1 Introduction

The primary aim of this thesis was to determine how knowledge is created in successful corporate R&D (Chapter 1, Section 1.1, page 4); the underlying assumption being that there is a link between the way in which knowledge is created and success in R&D). The reason for adopting this particular approach was the view that knowledge creation is the primary knowledge process driving corporate as well as academic R&D.

A further assumption made, and the reason for the focus on the UK pharmaceutical industry was that, relative to other industries, this industry would provide adequate examples of successful corporate R&D. The validity of this assumption was based on the significant consensus that existed at the time within the global scientific community, of which the present author was a part, that such was the case. This assumption was thus based more upon 'expert' opinion than upon comparative performance data. Nevertheless, the observation that a number of the larger North American corporations continued to carry out pharmaceutical R&D within the United Kingdom, despite the many changes that had taken place throughout the industry, was taken as a strong indicator that UK-based pharmaceutical R&D activities were effective. In addition, reports in the popular scientific press suggested that this assumption was somewhat justified. For example, in writing about the investment potential within the UK biotechnology sector, Coghlan noted that 'The land where penicillin was discovered has long been home to one of the world's most flourishing pharmaceutical industries' (Coghlan, 2003. p.55).

The final major assumption of this thesis relates to the way in which companies were sampled for participation in the empirical study. As will be explained in Section 4.3 below, companies were selected on the basis that corporate success is to some extent dependent upon success in R&D. Whilst accepting that corporate success may depend upon many factors (effective marketing, good sales skills, efficient operational practices, suitable strategy, etc.), the importance of R&D to corporate success was judged particularly high in an industry which is increasingly dependent upon the burgeoning science and technology associated with the human genome.

The key consideration for choosing the study of one industry relates to the very real practical problem of controlling extraneous variance which might induce error into the findings of any research. There are basically two ways to control such variance. The first is by the use of multivariate analysis (Sapsford, 1999, p.209), and the second is by homogenous sampling. This study chose homogeneous sampling for three reasons. First, it is much simpler conceptually. Second, it is, according to Astley, much less prone to error: as extraneous forces are not allowed to vary, they are not subject to any measurement error, and therefore cannot confound relationships between key sources of variation (Astley, 1978). And, third, homogeneous sampling controls variation which has not been identified, which was a particular concern in this present investigation.

Given the current state of theorizing and research into the impact of knowledge-based approaches on firm performance (Coates, 2001, p.9; Sohn, 2004, p.6), with the attendant difficulty of developing a set of hypotheses which would be tightly enough specified for the application of quantitative techniques, Section 4.2 makes the case for employing more exploratory techniques to uncover current practices and to try and tease out their

effectiveness rather than relate them to some hard performance measures. Section 4.3 then describes the method of sampling, and Sections 4.4 and 4.5 outline and discuss, respectively, the specific procedures employed in the collection of the data upon which this thesis is based, and the subsequent analysis of the data so obtained. Section 4.6 summarizes and concludes the chapter.

4.2 The Choice of Methodology

The choice of a particular methodology, as opposed to the choice of a method of collecting data, is to a large extent driven by the state of the knowledge domain which defines the field of enquiry at a particular point in time. This, in turn, has an impact on the kind of knowledge it is possible to produce at a given point in the development of the field which, in turn, impacts on both the methods and methodology which the researcher can employ. Basically, the state of knowledge may mean that is not always possible for a researcher to formulate a problem simply, clearly or completely. He/she may often have 'only a rather general, diffuse, even confused notion of the problem' (Kerlinger, 1969, p.18). It may thus take a great deal of exploratory work before a researcher can precisely formulate the questions to which he/she has been seeking answers. The diffuse stage of the knowledge in the emergent field of research that might loosely be termed 'knowledge management' (Beeby and Booth, 2000, p.75; Gupta *et al*, 2000, p.18; Davenport and Grover, 2001, p.3), means that this area of enquiry is in more a 'theory generation' than a 'theory testing' mode. This leads to the proposition that relationships between sources of variation are imperfectly understood and are therefore not capable of precise measurement. A quantitative data collection method is then inappropriate.

In rejecting a quantitative approach to data collection the researcher faces a set of choices for collecting qualitative data. These are to some extent bound in with the choice of source of data. Does the researcher, for example, become actively involved as a participant observer or action researcher of ongoing processes with one or more organizations? Alternatively, is it, for example, appropriate to use publicly available data in the form of narrative cases from either academic or other sources? As R&D work typically involves a

range of informal as well as formal approaches and practices, some form of 'observational' method was required. At the same time, it was the intention that, as far as was possible, the causes of and the meanings for what was being observed were established. A method involving a degree of adaptability in its application was then also needed.

For someone with an extensive knowledge base in chemistry it would have been possible to have engaged in direct observation and to have had a good understanding of what was being undertaken and why it was being undertaken, without running the risk of totally alienating the people being observed. However, gaining access to R&D personnel in their working environment is difficult. There are health and safety issues in allowing laboratory access to external personnel. Obtaining access to people actually doing the job would normally require that the participating company gain at least the perception of a recognizable benefit from the encounter. This might have proved difficult to justify. Observing R&D personnel might also have raised issues of being an insider, one who has a direct knowledge of process and practice. How might any previous experiences have influenced the way things were viewed? How much more (than with someone else) might subjects have been influenced? Also, would companies allow access to another scientist, albeit one now studying management processes? Confidentiality might well have been seen to be a problem and the situation was perhaps best avoided.

Since direct observation could have been problematic, some form of indirect observation was required. Requests for stories about product innovations might have provided some useful insights, but there would be no guarantee that the range of approaches and practices employed within corporate R&D would be covered using such an approach. At the same time, narratives are open to judicial editing. For example, stories submitted might have

been based upon the company's more successful rather than upon their more typical activities. They would also be recounted with the benefit of hindsight, which could cloud historic and contemporary issues (Sapsford, 1999, p.83). A technique that enabled the observation of current approaches and practices with some degree of control over the scope of the data collected was desirable. For this reason a direct interview technique was the primary method of choice.

The decision remaining is whether this technique should be structured or unstructured, the choice being rooted in the current state of knowledge in a field and the nature of the research questions. These being related to each other suggests that an unstructured technique would be effective when the field is seriously under-theorized and emergent and the researcher is tasked to use a more grounded approach to theory development (Glaser and Strauss, 1967), whilst a structured technique would be more effective when some theory already exists and/or the nature of the research question is clear. Unstructured interviews might have generated extremely interesting insights and would have perhaps had the potential to add something entirely new to the study of knowledge creation within corporate R&D. However, the practical constraint of time would have severely restricted the scope of any such interview. In addition, something that is appropriate in one setting will not necessarily be appropriate elsewhere. Applicability to other settings might have been difficult to validate. What was needed was a focus on the approaches and practices employed in R&D, but an openness as to what might arise. Semi-structured interviews employing open questions accommodate this stance. They also allow additional questions to be introduced, arising out of what is said, and according to the interviewee's willingness to offer additional insights. This was the approach adopted, and the following sections of this chapter describe the way in which this approach was applied.

4.3 The Choice of Sample

The case for choosing UK pharmaceutical companies was outlined earlier in Section 4.1 (page 125). However this industry is not as homogeneous as the appellation might imply. Companies within the UK pharmaceutical industry can be classified as pharmaceutical (prescription, and over-the-counter), biopharmaceutical (drugs developed using biotechnology techniques such as gene technology), biotechnology (supplying biology-based techniques), drug discovery research organizations (DRO), clinical research organizations (CRO), and formulation companies (manufacturers of pills and tablets). This study is based on data drawn from companies belonging to the first three categories only, the major corporate players in drug/therapy R&D, the selection being made as follows.

The 'FAME' (Bureau van Dijk) company directory (http://fame2.bvdep.com) was searched electronically in March 2001 for companies operating within the pharmaceutical sector in the United Kingdom. The result was a listing of 653 companies, 56 of which were identified as carrying out research and/or development activities. This excluded some companies known to the present author to be carrying out such operations, and this was despite the fact that these known companies were present in the full 'FAME' listing. Over a period of two weeks, the complete list of 653 companies was therefore checked for accuracy regarding research and development operations using prior knowledge, telephone, or website enquiry. Those companies not involved in research or development operations or no longer solvent were removed from the list, and merged companies were consolidated. This left a total of 64 companies. This updated list was further simplified by excluding (a) those companies acting as contract research organizations (DROs and CROs), since these are service organizations involved in only part of the drug/therapy

R&D process; (b) those companies dealing specifically with animal or veterinary health, in order to remove any variance due to, for example, the different regulatory requirements that might exist between animal and human healthcare; and (c) those companies dealing with diagnostic aids, drug delivery systems, and general medical materials or devices, as these activities are peripheral to drug/therapy R&D. The result was a list of 23 companies – 4 biopharmaceutical, 3 biotechnology, and 16 pharmaceutical – all involved in drug/therapy R&D. This list of 23 was augmented by a further 13 companies – 2 biopharmaceutical and 11 biotechnology – found by searching the scientific and business literature.

Since the main concern of this thesis was with effective knowledge creation in corporate R&D, a selection of those companies thought to have the most successful R&D was made from the 36 companies identified above. As there would appear to be no one proven or generally accepted measure of R&D success, for the purpose of this study, the decision was made to base R&D success on, what might loosely be called, the company's pro-activity within its industry sector. This was a composite measure based upon the company's ranking within its particular sector (pharmaceutical, biopharmaceutical, or biotechnology) as regards: (i) its quoted R&D intensity; (ii) the number of scientific papers published or presented in recent years, averaged for the number of R&D staff employed; and (iii) the degree of dynamism in the company's new jobs market. No scaling was applied. The reasons were as follows.

Quantitative measures such as 'number or proportion of products developed within the last five years' or 'number or proportion of products accounting for 80% of sales' are frequently quoted in the general management literature as measures of corporate success.

But there is a question as to the extent to which such measures are valid for R&D. Since many products can be developed from one initial idea or discovery, these measures might well be simply measures of successful development, including successful marketing or sales initiatives, rather than successful research and development.

A measure frequently used within the pharmaceutical industry is 'number of products in the R&D pipeline'. However, number of products in the pipeline is no guarantee of number of products eventually emerging from that pipeline and brought to market: attrition in pharmaceutical R&D is high. Also, such a measure is appropriate only for established organizations. Newly formed companies, such as those predominating in the biotechnology sector, may initially concentrate only on the research and development of one product. Yet, this can hardly be taken to mean that they are less successful in their R&D.

The UK government annually quotes figures for 'R&D intensity', expressed as R&D spending as a percentage of sales, as an indicator of R&D success, since this measure has been positively correlated in the medium term (3-5 years) with company performance measures such as sales growth, productivity, and market value (www.innovation.gov.uk/projects/rd_scoreboard/introfr.html). R&D intensity was therefore one of the measures adopted in this present study as an indicator of R&D success, although it should be recognized that, in absolute terms, such a measure highly favours the newly initiated research-based organizations where spending in R&D may or may not be high but sales are minimal or non-existent. In the pharmaceutical industry, R&D intensity is also heavily influenced by the costs incurred during the clinical trials stages, which may not necessarily be a good indicator of successful R&D: success is dependent upon positive trial results, but

many costs may be incurred to show only negative results. Rankings of R&D intensity were determined from figures quoted for the year 2000 (Stevenson, 2001, p.33).

Within the chemical industry, the number of patents published over a set time period has been used as a measure of corporate R&D success, but, as evidenced by the present author's experience, this measure suffers from the problem that some companies deliberately do not patent their most innovative ideas. The number of papers published or presented at conferences is also used as an indication of R&D success as determined by peer group judgement, but these papers can vary significantly as regards their content and ultimate value to science or technology. Like patents, they may also be suppressed for corporate reasons. However, companies within the UK pharmaceutical industry do generally record such publications in their annual company reports. This measure, with due regard to the type of publication or conference quoted, was therefore assumed to be valid for the purposes of sampling.

The final measure of R&D success – the degree of dynamism in the company's new jobs market – was suggested by the number of new R&D positions being created within the industry at the time of this study. New R&D positions, as opposed to replacement positions, were obtained from advertisements in the scientific and national press, and were assumed to be an indicator of a successful and expanding R&D organization, rather than one with simply a high staff turnover. Whilst not foolproof – companies do advertise replacement positions using new job titles – this measure was particularly useful in gauging the commercial potential and ultimate viability of the biotechnology organizations under consideration.

Upon the above basis, nineteen companies were initially contacted as possible participants:

2 biopharmaceutical

5 biotechnology

12 pharmaceutical.

The pharmaceutical group included three companies which were classed as being less successful according to the above criterion. These were to serve as controls.

Seven of the selected companies agreed to be formally interviewed. Informal conversations and conference presentations provided the answers for three additional companies. One participant from a further company agreed to be interviewed but had to withdraw because of work pressures. However in this last instance, and rather surprisingly, much of the information requested was later published on the company's website. These eleven companies provided the information upon which this thesis is based. They included six multinational pharmaceutical companies (the majority of the well-known companies operating in the UK and a little under half the possible population), one national and one international biopharmaceutical company (one third of those operating in the UK), and one large and mature and two small and young biotechnology companies (less than twenty percent of those operating in the UK). The pharmaceutical companies were AHP, AstraZeneca, Bioglan Pharma, Eli Lilly, GSK, and Pfizer. Included were the largest and second largest pharmaceutical companies in the world in terms of turnover. The biopharmaceutical companies were Antisoma and Celltech. The biotechnology companies were Amersham, Astex Technology, and Oxford BioMedica. It was believed that these companies were representative of their organizational category. Of the remaining eight companies contacted, two declined to participate, one was about to

close its UK operations, and five did not respond despite further written and telephoned requests. To preserve company confidentiality in the pages that follow, Company-A to Company-F designate the pharmaceutical companies, Company-G and Company-H refer to the biopharmaceutical companies, and Company-I to Company-K denote the biotechnology companies participating in this study. Only one of the 'less successful' pharmaceutical companies agreed to participate (Company-C).

During the course of this study, gaining access to biotechnology companies was particularly difficult. The business community in this segment was particularly fluid at the time and companies were continually being formed, acquired or dissolved. Small start-up companies had other priorities, and those involved in merger, acquisition, or dissolution were uncertain of their future and felt unable to participate. The larger biotechnology company involved in this study was a long established and successful multinational organization. The two smaller biotechnology companies interviewed whilst not financially sound in the sense that their turnover more than compensated for their expenditure were, nevertheless, well funded through venture capital, and appeared relatively stable in that they had been in existence in the United Kingdom for more than three years

4.4 Data Collection

Politeness required the first contact with a company's R&D personnel to be the R&D Director (or equivalent). However, for this study, R&D managers were the interviewees of choice, as these people were likely to have not only the subject specific knowledge and experience of interest but also the responsibility for and active involvement with the R&D unit. Thus, whilst their responsibilities would enable them to adequately portray the overall approach to R&D, their involvement and likely background in practical R&D would enable them to also portray the practice of R&D from the perspective of the R&D worker. In fact all interviewees did have previous experience working as R&D researchers or developers prior to becoming managers (or in one case a director) responsible for R&D. A final reason for choosing R&D Managers was that they tend to be more accessible than either R&D workers or R&D directors.

Potential companies were first contacted by telephone to ascertain their likely participation and, where possible, to gain a contact name. An interview request letter was then sent to prospective participants. This letter briefly outlined the reason for the request, the background to the study, the area of research interest, and the limits of confidentiality (see Appendix 4.1 for a specimen). Contacts who had agreed to participate were each sent a copy of the interview questions approximately one month prior to any interview. This was in order to check the viability of the questions in relation to their organization's activities, their own organizational roles, and any needs for secrecy or confidentiality. It also allowed participants time to undertake any necessary preparatory work prior to the actual interview.

Face-to-face interviews were carried out wherever possible, as it was felt that these would allow for the best possible understanding between interviewer and interviewee: non-verbal as well as verbal communication would be possible, feedback would be instant, and conversations could be allowed to progress as time and other constraints dictated. In practice, non-verbal signals were found to be particularly useful for saying the 'unsayable', although such signals are, of course, open to interpretation. 'R&D' and 'knowledge' mean different things to different people. This meant that although the same questions were asked in, as far as possible, the same manner, it was necessary on some occasions to adapt questions accordingly. There was thus the possibility that answers may sometimes have been influenced by the words used, although the uniformity of the answers supplied would suggest otherwise.

Interviews were carried out during the months of August 2001 to December 2001. As suggested by Miles and Huberman, time was allowed to assimilate the information obtained from one interview to enable emerging ideas to be explored in subsequent interviews (Miles and Huberman, 1984, p.53). Three telephone interviews (one a follow-up interview) and seven face-to-face interviews (including three interviews with different managers from one company) were conducted. Telephone interviews lasted approximately 45 minutes. Face-to-face interviews usually lasted between one and two hours. Since people's perceptions about particular approaches and practices can vary, the triplicate interviews were used to test for any differences between the views expressed by interviewees within the same company, and thus the validity of their responses. Although different aspects were sometimes emphasized, the responses from the particular company involved (Company-A) did turn out to be fairly uniform. It had been hoped that additional interviews within the other participant companies would also have been possible, but this

was not so. In one instance (Company-E) it was possible to compare the formal interview with some *ad hoc* conversations that occurred during and after a conference presentation. although in this case the people involved were from different divisions of the same company, one division dealing with prescription, and the other dealing with over-the-counter drugs. Personal experience did, however, suggest that the answers to the posed questions received from these and other participants did 'ring true'.

In line with the factors thought to be the most influential in determining how knowledge is created within R&D, the structured interview questions were separated into three sections:

(A) R&D approach

(B) R&D practice

(C) Knowledge working in R&D.

The actual interview questions are listed in Appendix 4.2.

The questions in the first section (R&D approach) were answered wherever possible by recourse to published data prior to any interview. This enabled the maximum amount of interview time to be spent discussing the meanings behind any observations, rather than simply checking the facts or observations themselves. Company annual reports, company websites, economic and market websites, and conference proceedings were the major publications used. As an example, company mission statements quoted on company websites often indicated whether the overall R&D approach was predominantly a marketing orientated (second generation R&D) or closer to a business integration (third generation R&D) strategy.

There were three main questions in the second section (R&D practice): (i) how are projects initiated, (ii) how are projects managed, and (iii) how are projects terminated? Combined with questions in the third section, these questions were used to determine how knowledge is created within an R&D context. Answers were descriptive, with some reasons suggested for the approaches taken.

Questions in the third section (Knowledge working in R&D) were intended to give an idea of the extent and purpose of the processes commonly referred to as 'knowledge acquisition', 'knowledge sharing', and 'knowledge application'. In particular, the degree of formality involved and the possible influence on R&D approaches and practices was of interest. Answers were mainly informed guesses, and a degree of subjectivity was perhaps to be expected.

Whilst there have been a number of reports in the literature benchmarking best practice in R&D (see, for example, Davidson *et al*, 1999, p.13), a final question was posed in an attempt to discover what R&D managers in the UK pharmaceutical industry contemporaneously believed to be the most important factor in the successful management of corporate R&D.

Semi-structured interviews appeared to work well. They enabled the answers to the predetermined questions to be answered within the time acceptable to most R&D managers, and they gave these managers the option of adding their own thoughts and opinions as they thought appropriate. Thus, the actual practices were described, the reasons behind those practices were sometimes given, and the effects caused were explored. However, the use of semi-structured interviews is prone to several dangers.

First, the questions presented might have directed interviewees towards giving the replies that they thought were needed (Sapsford, 1999, p.104). To counteract this possibility, interview questions were kept as open as possible. Second, the perceptions of interviewer and interviewee might vary. To reduce this possibility, factual questions were interposed as checks to perceptions, and the factual information so obtained was verified whenever possible with published information in company reports and accounts, and reports in the scientific and business press. Finally, focused interview questions may have meant that more important issues were missed. However, doing otherwise may well have extended the scope of the exercise to unmanageable proportions.

The questions highlighted in bold type in Appendix 4.2 were introduced into all interviews. The remaining questions were introduced as circumstances suggested. Further supplementary questions were asked when clarification was required or when they seemed appropriate to direct the flow of the conversation.

As noted in Section 4.3 above, the data from these formal interviews was augmented by data from three informal conversations and one particular website communication. Written notes were made during all interviews and conversations. Scheduled interviews were recorded on audio-tape when acceptable to the interviewee and when the necessary equipment was available (in all but two instances). Informal conversations were not audio-recorded. All formal interviews were transcribed within two weeks of the date of the interview.

4.5 The Method of Analysis

The final set of transcribed interviews, conversation notes, and website communication was analysed as follows.

First, the interviews/notes/communications were separated into groups according to the type of company being interviewed: pharmaceutical, biopharmaceutical or biotechnology. This was to enable any differences between these three industry sectors to be more easily observed. Differences might have resulted, for example, from the participant selection process outlined in Section 4.3 above, or perhaps from the science being applied. Might the selection process have resulted in an unfair comparison between young and old, or small and large organizations? Would, for example, the greater understanding that could be expected from the use of gene therapy result in a more traditional and 'managed' approach to the practice of R&D?

Second, for each group of companies, the answers to the individual questions were collated (or segmented) into corresponding answer sets.

Third, for each answer set, the answers were manually compared and contrasted for common themes and differences. These themes and differences were summarized in note form. These notes are outlined in Appendices 5.1 to 5.9. The interpretation or 'sense' made of the answers obtained, and the themes and differences so selected are, no doubt, to some degree subjective (personal), and for this reason the actual interview transcripts are available separately. The overall themes and differences are presented in Chapter 5. They provide the substance for the discussion on knowledge creation presented in Chapter 6.

4.6 Conclusion to the Chapter

This chapter began by discussing the assumptions made in the present investigation into knowledge creation in corporate R&D. These assumptions were: success in corporate R&D is dependent upon the way in which knowledge is created; UK-based corporate pharmaceutical R&D provides adequate examples of successful R&D; and corporate success within the pharmaceutical industry is dependent upon successful corporate R&D.

Given the emergent nature of the field of research into knowledge-based approaches on firm performance, the chapter then made the case for the use of more explorative techniques, and outlined the choices made in arriving at a semi-structured interview method for collecting data on the approaches and practices employed within pharmaceutical R&D. In choosing to observe through the words of R&D managers, it was hoped that any insider bias would be minimized. Whether, or not, this is so is difficult to verify. The researcher (the present author) did, however, believe that she went into these interviews with an open mind, and, as will be shown later, the major finding of this empirical work produced a result that was contrary to her pre-existing belief (Chapter 7, page 291). In this respect, it might be claimed that the design of the research was sufficient to show 'that the researcher's beliefs could be falsified by the evidence' (Sapsford, 1999, p.13). Semi-structured interviews allowed the direction that was needed to enable the required observations to be obtained in the time available. At the same time they left scope for further observations to be made at the interviewee's discretion. Thus, factors additional to those thought important by the present author could be and were introduced by managers currently working within R&D.

The use of semi-structured interviews provided data that was well-structured and fairly tight, and was thus amenable to manual analysis. However, the fact that the data made use of observations leaves the possibility that interpretation (on the part of both the interviewee and the interviewer) has played a part in the findings reported later in this thesis. Without the justification that might have been obtained through a quantitative test of a set of hypotheses, it is hard to see how this might be improved. But this then introduces the question of prejudice in any questions that might have been asked in such a set. What can be said is that, in the main, the interview questions posed were open, the answers obtained were fairly uniform, and the observations made 'rang true' to the previous experiences of the present author.

Organizations within the UK pharmaceutical industry are far from homogeneous in respect of their particular fields of activity. This study has investigated those companies typically classified as pharmaceutical, biopharmaceutical, and biotechnology which concentrated on human drug/therapy R&D. Companies were not specifically controlled as regards age, size, or structure, although pharmaceutical companies tended to be mature, larger and more hierarchical, and biopharmaceutical and biotechnology companies were generally younger, smaller, and organic. This could have led to extraneous variances which were not controlled within this present study. However, the separate analyses of these three groups of organizations and the similar findings obtained throughout would suggest that any such variances were insignificant for the purposes described herein.

Participant organizations were, with one exception, believed to be representative of those companies that operated successful R&D departments. Since there would appear to be no one proven or generally accepted measure of R&D success, this study chose to use a

composite measure based upon company rankings as regards quoted R&D intensity, the number of recent papers presented for peer review per number of R&D staff, and the degree of dynamism in the company's new R&D jobs market. The justification for this approach was based largely upon experience. However, it is perhaps interesting that the only company classed 'less successful in R&D' within this study was the one company that has since closed its operations.

Chapter 3 has shown us that the interpretations that we each make and the realities that we each construct are inherently personal to ourselves and are not necessarily the same as those made by or constructed by others. Chapter 5 therefore now attempts to outline the findings of the empirical research in a manner that is, as far as possible, free from personal interpretation. The discussion on knowledge creation within R&D, based upon the present author's interpretations of these findings, is reserved for Chapter 6.

5 THE FINDINGS OF THE EMPIRICAL RESEARCH

5.1 Introduction

The questions asked in the empirical study upon which this thesis is based were separated into those dealing with (a) the approach, (b) the practice, and (c) the knowledge processes used in R&D (Chapter 4, Section 4.4, page 139). This chapter follows this same order, with Section 5.2 describing the influences upon and the corporate approaches adopted in UK-based pharmaceutical R&D, Section 5.3 outlining the ways in which R&D is carried out, and Section 5.4 looking at the knowledge processes employed. Section 5.5 concludes with a summary of the main points of the chapter.

The companies participating in this study differed significantly in terms of their size, type, maturity, and geographic spread (Appendix 5.1, page A5). They varied between some of the largest pharmaceutical companies in the world, formed as the result of 'mega mergers' between large mature multinational companies; to medium and small biopharmaceutical companies with few products in the market place; to small start-up biotechnology companies turning little or no profit. They varied between those involved in chemical drugs; to those involved in biological therapies; to those involved with the technologies useful for drug or therapy discovery, analysis, or development. They varied between those that could carry out in-house all operational processes from drug discovery to product launch; to a semi-virtual company that outsourced most of its activities to others. They varied between those with their home base in the USA; to those with their home bases in Europe (the UK and Sweden). And they varied between those operating many R&D sites

throughout the world; to those operating only one site within the environs of another organization. In addition, whilst all companies claimed *overall* R&D strategies akin to business integration (third generation R&D), as intimated by previous reports (Chapter 2, Section 2.2.6, page 35), some tended more towards science/technology push (first generation R&D) whilst others appeared to be more market pull orientated (second generation R&D). At the same time, all companies participated in a range of collaborative ventures characteristic of fourth generation R&D.

Despite the differences that undoubtedly existed, distinct similarities could, however, be observed in the way in which all companies practiced their R&D and in the knowledge processes and techniques that they all employed. This chapter highlights these common themes, whilst noting some of the differences.

In presenting the findings of this empirical work, the view has been taken that research is not the same as development, and the later sections in this chapter have been segmented accordingly. This is despite the fact that with the present management fashion for 'cross-functional teams' and 'rugby scrum' approaches to new product development, we might perhaps be forgiven for assuming the contrary. Indeed, with few exceptions (see, for example, the work of Kumpe and Bolwijn, 1994; and Becerra-Fernandez and Sabherwal, 2001), the more recent literature in this field refers to R&D as if it is a single entity, or talks about the R&D process as if it is a single process (albeit involving several stages).

The justification for separating the findings for *research* from those for *development* is that companies that work in the pharmaceutical arena do in fact clearly separate research from development. They do this because research serves a very different agenda to

development: research is about the search for something new – the exploration for new knowledge; development is about the improvement of something that already exists – the exploitation of existing knowledge. These different agenda have important implications for the approaches and practices adopted in research and development. Sections 5.2 and 5.3 indicate that research retains the approaches and practices of first generation R&D, whilst development employs many of the approaches and practices associated with third and fourth generation R&D. Section 5.4 then shows that, as a consequence of these differences, the knowledge necessary for and created in research differs from the knowledge necessary for and created in development. And, whilst the processes commonly referred to as knowledge acquisition, knowledge sharing, and knowledge application play important roles in creating knowledge within both research and development, the techniques associated with these processes differ between these two activities.

All interviewees viewed their R&D operations as being important to the continuing success of their organizations – a perhaps far from surprising finding from R&D managers. Nevertheless, pharmaceutical R&D is important, not least of all because it is expensive: R&D costs were, typically, 15 to 17 percent of annual sales revenue in the larger mature companies and substantially higher in percentage terms in the smaller younger companies. Thus, although R&D cost structures vary across the sector, the costs incurred are substantially higher than those usual for most other UK industry sectors (2 per cent or lower).

Research is fundamental to the pharmaceutical industry for sustaining the momentum associated with competitive innovation, and it is difficult to blend the inherently uncertain

process of what we shall later see is best described as transdisciplinary Mode 1 type discovery as if it were a subset of the comparative certainty associated with the evolution of market-rational user-needs. As an aside, it is interesting to note that the one company in the present sample classed as 'less successful' emphasized development over research, adopted a stronger leaning towards a market-pull approach, and had a seemingly reduced tendency towards the formation of collaborative ventures and the allowance of individual networking. These factors are not discussed further within this chapter, but they have, nevertheless, been influential in considering the management of R&D discussed later in Chapter 6.

5.2 Corporate Approaches in UK-Based Pharmaceutical R&D

5.2.1 The Most Important Factors Influencing Corporate R&D

From a strategic perspective, commercial viability was the factor most frequently mentioned as becoming increasingly important in justifying research as well as development expenditures (Appendix 5.9, page A35). Government pressures to reduce prices, combined with the threat of generic competition, even before products come off-patent, have meant that, moral issues notwithstanding, companies now tend to channel most of their R&D efforts into only the most profitable treatment areas:

> 'The increasing pressure from outside on commercial viability … is probably the most important thing, because all the other stuff we'll focus on anyway. Everybody likes doing science here and all the other things, but if you don't focus on the commercial stuff you're not going to be in business very long.' Company-A-4, p.12

From a management perspective, a clear focus, a flexible approach, and a culture of experimentation were the factors most frequently mentioned as being important in research (Appendix 5.9, page A34; Kanter (1983) and Leonard-Barton (1995) Chapter 2, Section 2.3, page 38). A clear focus is important so that everyone knows what the research is trying to achieve and what their particular role is in helping to reach that achievement:

> 'I think it's focus, it's knowing what you are trying to achieve, and for everyone in the organization to know their part in that, their role in that. All the other things [come] to nothing if they're not all on the same side, if they are not all heading in the same direction.' Company-B, p.27

But, at the same time, a flexible approach is needed to manage the balance between shaping research and allowing the experimentation that is needed to make it happen:

> 'You can't manage [research] as tightly as you can manage development activities or production activities or whatever. You have to accept that there are going to be blind alleys and there are going to be backtrackings and sudden breakthroughs ... You have to allow enough flexibility. So I think it's managing the balance between trying to monitor and shape what's going on in research and giving people the creative flexibility they need.' Company-G, p.27

Teams of people (Appendix 5.9, page A34; Chapter 2, Section 2.3.2, page 64) and a clear project plan that everyone had 'bought into' (Appendix 5.9, page A35; Burton *et al,* Chapter 2, Section 2.3.2, page 66) were the factors thought to be most important in development. Since pharmaceutical development *is* now very much a multidisciplinary and multifunctional activity (see Section 5.3.2, page 168), or more accurately a transdisciplinary and transfunctional activity (Chapter 6, Section 6.3, page 219), it is perhaps no surprise that teams of people working together were thought to be particularly important during this stage:

> 'The whole business revolves around teams of people. The task is far too big for any one individual or any one group now.' Company-A-4, p.13

> 'I just see the whole process as a team knowing what they are going to do, and they've all got the same colour shirt on and they know who is defending and who is attacking and so on.' Company-B, p.27

And, because of the need to remain commercially alert, a clear project plan is needed to clarify what needs to be achieved, how the work is to be attempted, and what the outcome is likely to be after a particular time interval. At the same time it was emphasized that all participants to the process should be involved in the production of this plan, and should crucially be able to 'buy-in' to it:

> 'A clear project plan which everyone is working within, a plan that everyone has bought-into, so, this is what we're going to do, this is why we're going to do it, this is how we're going to do it, and this will be the outcome at this time. And if that level of clarity is there, it makes it much easier to manage the entire situation.' Company-C, p.10

The importance of communication (Appendix 5.9, page A34) is perhaps an indicator of the importance of knowledge processes to R&D. Effective communication at all levels with people inside and outside the company was perhaps *the* most often quoted factor for the successful management of R&D (and beyond). Imparting a clear focus, combined with the need for flexibility in research and working in teams in development requires effective communication between all participants to the R&D process and at all times:

> 'Communication is probably key. Our chief executive … says, 'We're not selling drugs, we're selling knowledge'. And, I think on every step of the way communication is the big thing.' Company-H, p.18

5.2.2 Approaches to Research and Development

The increasing importance of commercial viability noted in Section 5.2.1 above (page 150) is clearly evidenced by changes in companies' mission statements. These invariably used to make reference to 'meeting unmet medical needs': essentially a science/technology led or first generation R&D approach. For example:

> 'Our global quest is to improve the quality of human life by enabling people to do more, feel better and live longer.' (Company-D, Half Year Report, 2001, page before p.01)

Since disease and illness is a global affair, these mission statements translated into a global approach towards research. The large pharmaceutical companies in their annual reports outlined global research strategies in line with their overall corporate strategies, and biopharmaceutical and biotechnology companies pursued their research expertise on the world stage with global partners. However, at the same time there was and is no universal procedure for the acceptance of safety and efficacy in drug usage. Whilst information may be universal, the knowledge associated with that information and incorporated into local

healthcare requirements is not necessarily so. The result is that companies need to meet the healthcare rules and regulations of each of their target markets before candidate drugs can be tested, authorized, and sold to human beings within those markets. Whilst research strategies were on the whole global, development strategies also needed to take a more local perspective (Appendix 5.2, page A9).

The costs of drug R&D are high (typically of the order of US $500 million plus), and ongoing since drugs are continually regulated throughout their lifetime. Prices were high in order to recoup costs. But, the increased pressures on companies to reduce these prices led first to company mergers and acquisitions to yield economies of scale and scope, and second to rationalization of R&D activities to further reduce costs. Whilst still making reference to improving life for others, more recent mission statements have consequently changed to reflect a business integration or third generation R&D approach. For example:

> 'We will become the world's most valued company to patients, customers, colleagues, investors, business partners, and the communities where we work and live.' www.company-a.com/are/mn_about_mission.html, January 20, 2003

Whilst development strategies are now highly influenced by commercial considerations, research strategies do, however, retain a high degree of science/technology push. This difference was attributed, in part, to the fact that the greatest proportion of the cost of 'R&D' is in development: the cost breakdown normally quoted is 10 percent for research and 90 percent for development. And, importantly, it is recognized that channelling research efforts too early can restrict the options available for later stage developments:

> 'Discovery, by the nature of things, you know, being a chemist, you can't channel people too much at the beginning. There is a certain amount of serendipity, and inspiration is very important. So things are a little bit diffuse in research. But gradually as [projects] get through – and there are decision making bodies such as the research management team, the development management team and then the group commercial development management

> team – all the time decisions are taken [at the various levels], and they will look at the portfolio and decide what should carry on.' Company-H, p.5

At the same time, because most of the biological processes in the human body have more than one impact, work at the research stage may yield knowledge that can prove useful across a wide range of therapeutic areas. At the very least it will increase the understanding of how the human body works. Science and technology *is* of fundamental importance to corporate pharmaceutical research:

> 'What we are looking at is understanding biological processes at the molecular level … so you can understand how a disease progresses. If you understand that, you can look at ways in that metabolic process or that biochemical pathway that you can influence. And there are always loads of ways in which you can do [that]. For instance … if you look at the cascade of events that leads to the control of blood pressure there's loads of feedback mechanisms.… So if you try to interact at a certain point it could stop everything that goes on afterwards, or it could change it to another process, or it could affect one thing without another, because most of the biological processes in the human body have more than one impact.' Company-B, p.10

Nevertheless, commercial pressures have meant that, in recent years, even research strategies have tended to concentrate more on meeting the more lucrative age-related medical needs of Western markets (heart disease, diabetes, etc.) where prices can be levied so that profits are high and costs can be more than recouped. Research and development into cures for predominantly third world diseases have been limited and have usually been at the instigation of the World Health Organization and similar entities (Hayman, 2002, p.12; Rappuoli, 2002, p.25; The Economist, 2003, February 1, p.60 and December 6, p.12). This has raised the issue of the moral right of developing countries to access the medicines they need, at prices they can afford, to support the lives of their citizens. There have been some moves by the larger Western organizations to take this issue on board, and some drug prices have been reduced to certain areas of the world. But this has been largely because of the threat of, or the actual loss of, sales to generics companies who are able and willing

to manufacture substitute product at marginal cost and often before patent expiry. These companies can, of course, do this because they incur none of the costs and none of the risks associated with drug R&D.

R&D rationalization has resulted in the larger companies operating semi-autonomous research units. These units generally have autonomy within a particular therapeutic area with global objectives for that area (Appendix 5.2, page A10). Thus, there has been a change from an approach of trying to do everything and anything on any one site, to accepting that one site cannot do everything, and what it does do should fit with corporate strategy. Thus, there has also been a change from allowing or even encouraging internal competition between units to a more collaborative approach between units, a decidedly more efficient approach to using the resources available:

> 'We are talking about 6 years ago … There was a period of three or four years when there … was a competitive autonomous set of R&D sites. If you think about it, it's a pretty stupid thing to do, to have competition within your own organization. I think challenging each other's site to be good and be better, that's one thing. That's like having fifteen players and choosing the best eleven. And I think that's fine. But [the individual sites] saw the other sites as their competitors. They didn't see [other companies] as their competitor[s], they saw the other parts of the organization, which I think was pretty pathetic … So that's the old model. The new model is this autonomy, certainly autonomy where you have an allocated area within which you can work.' Company-B, p.7

Development units on the other hand tend to be more general and cover a range of issues and therapies of relevance to the local region (Appendix 5.2, page A10).

In one respect the research units of the larger pharmaceutical companies are now similar to the units of the smaller and younger biopharmaceutical and biotechnology companies: they have a clear knowledge area (or areas) on which to concentrate and for which they are held entirely responsible. In other respects they differ from the units of these smaller

companies: they have formal links to a number of in-house units working in a variety of different areas; and they are supported by units providing specialist technical and analytical services (Appendix 5.2, page A7). The extent to which the in-house services are an advantage over external providers is perhaps reflected in the esteem in which they are held: in most cases this appeared to be high. In turn, this is perhaps a reflection of the greater understanding that can be achieved within the same organization that 'speaks the same language' than can be achieved between organizations that hold different views, take different perspectives, and have different priorities.

The need for formal processes of coordination tended to be higher in the larger, more mature companies where it is simply not possible for everyone to know what everyone else is doing. Coordination in smaller and younger companies is loose and relies to a large extent on personal contact:

> 'It's relatively easy when the company's small because if there's only ten or twenty of you then you're always bumping into each other, and you can say the mean free path between persons is sufficiently small that you tend to interact and you know what's going on. So communication and networking around the organization is dead easy. It's only when the company starts to get bigger and … you get to the point where you see [someone] and you think, "Well who's he?" Well we're just going through this process … So we're already grappling with the problems of expansion and how you make sure the things you were able to capture and manage at the small stage you don't lose as you get bigger. And it's not rocket science, but it's a lesson that so many people have been through and everyone still gets wrong.' Company-I, p.2

Although the type of work undertaken has affected the choice of R&D location, the actual choices made would appear to depend upon more than the simple trade-off between supporting either market demand or technology supply as suggested in the previous literature (see Chapter 2, Section 2.2.3, page 24). For example, R&D in the pharmaceutical companies was historically located with or close to pharmaceutical production, and production sites tended to be where there were tax breaks. This is also one

reason why there are now a number of pharmaceutical manufacturing and R&D facilities in Ireland. In turn, production sites were traditionally located at the mouth of a river estuary, where waste and effluent regulations were generally less severe (Company-A-4, p.1). R&D locations may also be determined by closeness to external support facilities (specialist equipment, animal house facilities, hospital clinical facilities, etc.). The clustering in the Thames Valley and Cambridge regions in the United Kingdom was said to be, mainly, for this reason. Location decisions may also be influenced by other factors such as the perceived need to be near the organization's financial backers (Company-G, p.7).

Nevertheless, the capacity of researchers to participate in the act of discovery is shaped by what they know. Where they are, in a geographical sense, can shape how they learn what they know, and all companies emphasized that the existing knowledge and expertise at a location would be a contributing factor in determining the choice of site and the type of work (research and/or development) carried out at that location (Appendix 5.2, page A10). With the introduction of research specialization, the larger companies *have* therefore tended to locate their more recently established research sites close to relevant external 'centres of excellence', ostensibly to facilitate easy recruitment of knowledgeable and experienced personnel. In this respect, the UK is still seen as an important location by some companies because of its excellence in pharmaceutical and related research and the availability of a highly skilled workforce (Loftus, 2001, p.88). However, it is possible that this will change. The continental European countries are now spending relatively more on healthcare R&D than is the UK. As evidenced by the number of job advertisements in the scientific press, continental European companies would also appear to be poaching research personnel based in the UK. In addition, the relative ease of merger and

downsizing has resulted in there being now only one *major* UK 'owned' pharmaceutical player, whereas six years ago there were five. And, there has been a decrease in the world educational ranking of UK schools (The Economist, 1997, March 29, p.25; 2001, September 22, p.34; and 2003, April 19, p.25). All of these factors may be expected to have an effect on the ability of UK institutions to continue to carry out world class pharmaceutical R&D, even though government edicts continue to suggest that this sector of research remains a priority. Indeed, the fact that many external 'centres of excellence' are now located in the USA is perhaps one reason for the recent trend by companies to relocate their R&D headquarters there (Appendix 5.1, page A5). Other reasons may include the wish to (a) improve their profile in the largest drugs market in the world and/or (b) distance themselves from the 'animal rights' activists who have become particularly vocal and disruptive in the UK in recent years (Chemistry in Britain, 2001, March, p.5; and 2003, June, p.5).

UK Biotechnology spin-outs have tended to locate close to their original sources of inception, but more than one interviewee felt that this might become less important as the spin-out companies establish themselves as 'centres of excellence' in their own right (Appendix 5.2, page A8). Being close to a centre of excellence in a particular knowledge area is then not as relevant as the ability to use and expand upon existing knowledge and create new knowledge in order to produce something new. Thus, neither established nor newly formed organizations believed that geographic proximity between internal and external workers was a particular requirement for successful research. The view expressed was that, since scientists regularly attend conferences and 'talk' over the Internet (Appendix 5.7, pages A23 and A29, respectively), technology spillovers (Chapter 2, Section 2.2.3, page 24) occur, come what may. However, distance is relative, and,

compared to some countries in the world, anywhere within the United Kingdom could perhaps be thought of as 'close'. At the same time, increased global interconnectedness can decrease any effects that distance might cause.

In contrast to the literature reports (Jewkes *et al* (1958), Gibbons and Johnston (1974), Chapter 2, Section 2.3.1, page 43), interviewees felt that government initiatives had little influence on research activities at a particular location, except possibly in a negative way:

> 'It won't be that you'll start to do some work in a particular area because someone said it's trendy, or it's good, or whatever, or here's some ideas. But what you would do would be to *not* start work in a particular area if it was felt that it was going to be controlled in a way that would stop you making a profit for instance. And genetic modification would be an example where you might say, 'Actually we don't want to be in this field'. I am thinking not particularly of our industry, but an industry like agrochemicals, where if you can't do the trials, if the government's not amenable to doing the trials, how on earth are you going to prove that you've got something worth selling.' Company-B, p.14

For development purposes, proximity to the relevant regulatory authorities (Chapter 2, Section 2.3.2, page 64) was, however, thought to be important in aiding 'drug approval' since it increased the scope for face-to-face trust building and understanding:

> 'The regulators are heavily involved … They know what we're doing and we can get input from them on whether we're going in the right direction to actually get something approved. That's obviously, in terms of the whole lifecycle, quite late on in the process. We don't go to them in discovery and say we're thinking of discovering some drugs … but certainly when we get into development, this is straight across the world now, we go and look at the major regulatory agencies and involve them in what we're doing.' (Company-A-4, p.6)

Where it had occurred, the internationalization of R&D was seen as an advantage: it allows companies to recruit the most knowledgeable and most experienced scientists available for research (Company-B, p.4), and at the same time allows local development activities to concentrate on national or regional health priorities and regulatory requirements (Company-B, p.5). In effect, it enables a much greater use of global knowledge, and at the

same time brings diversity and the full range of talent into R&D. Where R&D internationalization had occurred by merger, knowledge acquisition was seen as an advantage gained (Company-H, p.11). The interviewees from those companies that had not yet internationalized their R&D operations foresaw similar advantages to those given above. However, they also suggested that the disadvantage would be the loss of a 'family' atmosphere and approach (Appendix 5.2, page A9).

The R&D sites of the larger companies carrying out both research and development can perhaps be seen as a compromise between the needs of research and the needs of development, with the needs of the former taking precedence in recent years.

5.3 R&D Practices in UK-Based Pharmaceutical R&D

Drug R&D is by necessity a staged process, ultimately involving several phases of increasingly expensive clinical trials, each of which must be completed before the next is allowed, and before product can be released for human consumption. However, in all of the companies interviewed, it was emphasized that there was a clear distinction between the work classified as 'research' and that classified as 'development', to the extent that research units are functionally separate from development units. Although they may be located in the same building or complex of buildings, with contact occurring between the two sets of workers, research units were also said to have completely different management structures and approaches to those of development units (Appendix 5.3, page A13). The stages typically involved in drug research and drug development are outlined in Figure 5.3.1 (below).

Drug Discovery: First Patent → Lead optimization → Clinical trial → Concept testing →

Drug Development: Product licence → Clinical Development (Phase 1, Phase 2,

Phase 3 Toxicology and Pharmacokinetic studies) → Pharmaceutical and Analytical development → Process Chemistry and Manufacturing → Registration and Regulatory affairs → Sales and Marketing (preparation, promotion, advertising and selling) → Product life cycle support.

FIGURE 5.3.1: TYPICAL STAGES IN THE DRUG DEVELOPMENT PROCESS
Adapted from the AstraZeneca Annual Report, 2000, p.17

The present findings thus suggest that research and development each generates its own distinctive work culture. One interviewee remarked that he believed these cultural differences were, in part, a consequence of the huge sums of money needed for drug development, as opposed to drug research:

'It took me many years to understand the difference … there's a very big difference in the way they think, the way they work … In discovery … people can say this is the case, and they'll argue until they are blue in the face, and they'll try to do the experiments to prove one way or the other. But in development they are much more keen to avoid being seen as the person who brings a product down, or who's fault it is that a product fails … [So] you can bring forward development into research and you can keep on doing research in development, but there is a point where major investment kicks in, so there's a different culture kicks in at that point.' Company-B, p.1

But perhaps these different cultures exist as much because of the different skills and requirements involved:

> 'You have research which is really coming up with the new chemicals and getting them to proof of concept, and then you have development which is charged with actually getting them approved onto the market place (Company-A-1, p.2)… rounding up all the resources to produce the data the regulatory authorities need to know.' Company-A-1, p.7

The pharmaceutical industry is understandably a highly regulated industry. The disciplines needed to take a candidate drug through extensive clinical trials to ensure safety to humans or animals are different to those needed to discover candidate products in the first place. It is perhaps hardly surprising that companies separate creative discovery from regulated development.

5.3.1 Project Initiation

Research

Whilst agreeing with the view that ideas for research projects might come from anywhere (Leonard-Barton, Chapter 2, Section 2.3.1, page 43), all interviewees stated that the move into product development is ultimately dependent upon there being a fit with corporate strategy and a balance between technical feasibility and commercial viability (Appendix 5.3, page A11). The extent to which each of these factors influence research activities in the early stages is, however, hard to quantify. Certainly, most companies initially appear to adopt a high degree of science/technology push (first generation R&D) rather than a market-pull (second generation R&D) or business integration (third generation R&D) approach:

'We used to do anything, but now there are strategic areas that we will look at … We rely on our clever guys in discovery to look at areas of relevance to the company.' Company-A-4, p.2

'Projects come from wherever you think there is a chance to make a difference. Likely sources nowadays are biological innovations. [Products come from] understanding biological processes at the molecular level … [we are] looking at ways in which we can modify [disease-associated proteins] to affect the progress of a disease.' Company-B, p.10

'Ideas can come from anywhere. And good ideas can be tested informally as to their feasibility. However, in order for an idea to become a project it needs to fit with our corporate strategy.' Company-C, p.3

'The new company with a range of experience in emerging technologies will possess significantly enhanced scale and scope to discover, develop and deliver new and better medicines in a faster and more efficient way.'
Company-D, Annual Report, 1999, Note on the 'Merged Company'.

'Everything … begins with the unmet medical needs of people.'
www.company-f.co.uk/international/index.html 5th April 2001

'We've got people who … trawl round for interesting molecules … and licence those in.' Company-G, p.1. 'The focus is on oncology.' Company-G, p.3

'Before the merger, [Company-H] … tended to discover drugs in any indication, take them through to 'proof of principle', and then would get a partner who was a large pharma… [Now] rather than research going into any area where there is an opportunity, we would try and focus into the particular disease areas which we could then take through development and then take on to our group to sell.' Company-H, p.4

'There is a creative tension between what is seen to be a research opportunity and between what is seen as a market opportunity or a business opportunity … Projects may be research driven (the scientist reads a paper and has an idea) or business driven (the business people see a big opportunity), but ultimately there needs to be a balance between technical feasibility and commercial viability.' Company-I, p.1

Work is focused on the 'visualization' of therapeutically significant protein families with a view to finding primary binding domains, and hence target drug candidates. Company-K, p.2

It is interesting and perhaps a little surprising that those companies that are more vocal in advocating science/technology push are those that are currently favoured by the UK financial houses. There will, of course, be many reasons for a company's stock market valuation, but one of the deciding factors for mature companies working in the UK pharmaceutical sector would appear to be the number of products that the company has under current development (that is, in its pipeline). And, a science/technology push approach would appear to increase this number. Rightly or wrongly, Company-D's low London stock market valuation in 2002 (relative to other companies in the pharmaceutical industry) was attributed to the absence of sufficient products in the company's pipeline.[14] Such a valuation is not of course possible for a newly forming company. In this case, valuations reflect the company's business plan, its management team, and the potential of its patented technology (Company-I, p.18).

[14] It may be remembered from Chapter 4 (Section 4.3, page 133) that the number of products in the pipeline is no guarantee of the number of products eventually emerging from that pipeline.

Science and Technology Advisory committees consisting of eminent scientists and medical clinicians from the leading institutions around the world form part of the management structure in most of the companies studied. The role of these committees is generally strategic in nature. For example:

> 'A Science and Technology committee reviews and makes recommendations regarding the company's strategic research goals and objectives, and reviews new developments, technologies, and trends in pharmaceutical research and development.' Company-F, Annual Meeting of Shareholders' Proxy Statement, 2001, p.12
>
> 'A Science Advisory Board advise the executive management on science policy and strategy.' www.company-j-1.co.uk/about/index.html 16th November, 2001
>
> 'Ultimately, the decision on the company's strategy progression is decided by the board of directors [Company-I, p.9] … A Scientific Advisory Board contributes scientific knowledge and expertise, generally on a one-to-one basis.' Company-I, p.30

Full project initiation in research is largely the province of in-house technical and commercial teams:

> At the 'idea' stage this could be an individual or team effort. When an idea becomes a project, then that is run by the Director of Research and his various deputies. Projects are then a team approach. Team members include people from the research, development, safety, and regulatory sections.'
> Company-C, p.3

But:

> 'More and more, people are being influenced by what is commercially viable. So whereas a few years ago it might have been, 'This is a great idea and we can make the drug,' it's become, 'Can we sell the drug at the end of the day?'
> Company-H, p.6

The main drivers for the research undertaken in the large mature pharmaceutical companies are the outcomes of external research by universities, research institutes, and biotechnology companies (Jewkes *et al,* (1958), Gibbons and Johnston (1974), Chapter 2, Section 2.3.1, page 43). The needs of patients and general practitioners may also influence project initiation, as can organizations such as the World Health Organization. Suppliers

can, rarely, influence project initiation. The large mature biotechnology company noted similar influencers. In contrast, the larger biopharmaceutical company felt that although it was unusual to get an idea from a university or research institute, these institutions do very much help in the early development stages. Partner companies who are the bank rollers are the strong influencers for the work undertaken by the smaller biopharmaceutical and biotechnology companies (Appendix 5.3, page A11). Although clearly there are regulatory issues that need to be considered and grants that may be available, all companies interviewed felt that governments had little influence on specific project initiation (Appendix 5.3, page A12). In addition, the ability of any 'lead user' (Chapter 2, Section 2.3.1, page 48) to conduct its own work (and thus influence R&D activities) is severely limited by legal and ethical restrictions. It was also noted that it is not uncommon for previously failed products to later find commercial success. However, in this case, patent life considerations play a significant role in project re-initiation (Company-A-4, p.7).

Development

Drug development follows initial clinical trials and concept testing. Projects may arise from either in-house or external research. An actual or anticipated business advantage is crucial for this extremely expensive stage of the process, as is also a clearly defined route to commercialization:

> 'Successful [development] projects have a good business case, a defined scope, a delivery strategy, and controlled delivery.' Company-D, p.3

A formal project proposal will normally be submitted for board or management approval before the commencement of any work. This proposal will then be vetted for its development worthiness by a team consisting of research, development and

commercial directors, managers, or staff (cf. third generation R&D). Unless a science or technology can be shown to be of significant importance to the future of the company, commercial factors will normally take priority over technical interests.

5.3.2 Project Management

Research

All interviewees remarked on the need for a flexible, non-bureaucratic management approach in the early stages of research (Burns and Stalker, Chapter 2, Section 2.3, page 38), with feasibility studies being the province of research staff, whether individually or as a small team; such staff often being responsible for both the strategic and operational elements of the work that they undertake (Appendix 5.3, page A14):

> 'You don't want to make it too rigid. You don't want to make it too bureaucratic so that if [someone] has an idea then they're allowed to make the idea, they're not criticized as if they're wrong. And, you haven't got ten committees to go through before somebody says, 'Yes that's a good idea'. [Company-I, p.2] ... 'These people are clever people, they know what's needed, so they learn, they adapt.' [Company-I, p.5]

The process in the early stages is often unclear or fuzzy:

> 'I don't think there is necessarily an absolute set of 'rightness' just a consciousness that we're here, we're aiming to get over there, and we're trying to get there via the most direct route. It doesn't mean to say that there is one fine way of doing it, there's going to be a number of ways of doing it.' Company-I, p.11

Management's role is more one of facilitation and coaching:

> [During feasibility studies] we encourage people to say what it is they are trying to do, and they will then get the nod.' Company-B, p.11

Once an approach has been validated, or when specific drug compounds are being made or a technology needs extensive evaluation, projects were said to become a multidisciplinary team effort managed by a project leader, overseen by a research director, and ultimately controlled by a research management committee (Appendix 5.3, page A14). In the larger companies, this committee usually consists of the managers or directors of the various technical departments such as biology, biochemistry, chemistry, etc. In the smaller companies, the corporate management team or, rarely, a science advisory committee acts as the research management committee. Projects are then reviewed on a regular basis to determine continued viability (Appendix 5.3, page A14). In the early stages, continuance is based mainly upon expert technical judgement rather than on strict milestone commitments. In later stages, continuance depends upon the ability of the research to meet initial clinical trials.

Development

Drug development involves product licensing, followed by three phases of toxicology and pharmacokinetic studies, pharmaceutical and analytical development, process chemistry and manufacturing, registration and regulatory affairs, the production of information for marketing promotion, and life cycle support of the resulting product (Figure 5.3.1, page 161, above). Although the process is essentially linear, development is very much a team effort with people from the different scientific disciplines working together with production, regulatory, and marketing personnel (Chapter 2, Section 2.3.2, page 64) to bring product to market in the shortest possible time. As noted in Section 5.2.2 (page 156, above), in the larger pharmaceutical companies, specialist technical units (bioinformatics, high throughput screening, structural chemistry, etc.) may support the work undertaken.

Teams are thus multidisciplinary and multifunctional, and in the larger companies can be multi-site. Teams may also include members who are external to the company, as some or all of the work may be outsourced or carried out in partnership with others (Chapter 2, Section 2.3.1, page 52). Outsourced activities typically include product formulation; product manufacture and packaging; and studies of stability, pre-clinical safety, and toxicity. Collaborative partnerships are outlined in Section 5.4.2 (pages 200-202, below).

In line with Mode 2 working (Chapter 3, Section 3.4.1, page 103), the development team make-up may change with time, with research staff giving way to commercial staff as the project progresses to completion. Alternatively, there may be two teams, one involving a partnership with commercial colleagues and focusing on strategic elements, and the other focusing on the operational side and responsible for delivery of all the data needed for regulatory approval (Company-A-1, p.9).

Matrix management is employed in the larger companies, and project control predominates over technical or marketing control (Appendix 5.3, page A13; Henderson, Chapter 2, Section 2.3.2, page 65). Email, electronic conferencing, teleconferencing, and travel are used to aid, what is, in essence, a transdisciplinary approach (Chapter 3, Section 3.4.1, page 103). Cost and time estimates are deduced from the scope of the project and the resources available. Critical issues are highlighted. The objectives, common or shared targets, goal posts (which markets, actives, doses), risks, and assumptions are provided to all involved (Company-E-2, p.3).

Project managers usually hold the budgets and are empowered and are held accountable for project decisions:

> 'The project managers, who are the group I control, hold the budgets. So they are really given the authority to make the decisions. They are empowered and they are also accountable ... If there is any conflict between projects then they would go up to the Development Management team meeting. It would be discussed there ... where the priorities should be.' Company-H, p.4

However, as pointed out by several interviewees, it is the functional line managers who are usually responsible for allocating staff to the development teams. These managers consequently have a strong influence over project 'time lines' and ultimate success rates:

> 'It's more that you've got to bring people together based on their technical expertise. You've therefore got to rely on the lines to actually formulate who is on your team.' Company-A-1, p.10

With only a finite number of staff to be spread across a range of projects, the luxury of forming teams from staff having the most appropriate personality characteristics (see, for example, the work of Belbin, 1981; Roberts and Fusfeld, 1981; and Hurst *et al*, 1989) in addition to the necessary practical skills is non-existent. Instead, what at least one company does attempt to do is to bring the latest 'best practice' to newly forming teams by pursuing cross-team participation (see Section 5.4.2, page 191, below).

Despite basing team membership on technical ability (and, when conditions allow, perhaps an assessment as to who will work well with whom), the most common problem observed with this type of team working was linked to the fact that people on multiple teams can have conflicting work commitments:

> 'It's not ideal in that you get people that are on multiple teams across different areas and therefore have conflicting agendas.' Company-A-1, p.9

The advantages include the diversity of different viewpoints as new members join, and continuity when people bring their experience into play in different teams:

> 'You have some people that are on both of those teams in full development, which can be helpful because obviously you have got that extra level of

continuity, but equally you are then lacking bringing extra perspective to the table.' Company-A-1, p.9

Matrix management also allows for 'easy' exchange of resources between sites:

'Even within the specialties we often need resource from the other site for one reason or another, and so with matrix management it's quite easy to chop and change between sites. The fact that they're geographically adrift doesn't necessarily matter.' Company-H, p.4

In the larger companies, the continuation of a development project is subject to the approval of a Development Management Committee (possibly with sub-committees for specific areas or activities). In smaller companies, this may be left to the technical director or technical manager, the science advisory team, or more usually the general management team. Although it is not possible to predict the exact outcome of clinical trials, at this stage the route is fairly well defined and progress can be evaluated against target milestones.

Moving from research to development thus increases considerably the ability to control the work undertaken. Development projects can be managed in the traditional sense: they can be defined, designed, scheduled, implemented, monitored, reviewed and controlled (Company-E-2, p.4). Project management tools, such as Microsoft Project®, are often used as aids in managing this process (Chapter 2, Section 2.3.2, page 69), and have been said to increase intra- and inter-departmental awareness of what is being done, why it is being done, and how much it is likely to cost:

'I think that it has improved the way we do R&D because everything's become more transparent. It's not suddenly a black hole [that] money goes into and there doesn't seem to be any return at all until the commercial side has got hold of the product. It's now much more transparent, where you know what R&D are working on, where the money is going, etc. Certainly pieces of software like Microsoft Project® have made it much easier to plan out projects. And you can actually produce a visual image of what the project looks like, which I think helps people to see what it is that's being done.' Company-C, p.10

In some cases, subject to management approval, the project teams themselves set project milestones and deadlines. This was said to encourage the setting of more realistic time lines and improved resource allocation decisions. It was also thought to have increased team commitment (Company-E-2, p.6). Thus, rather than being simply a method of control, the use of this software had enhanced coordination and participation (McKinlay, 2000, p.109). Rather than being simply a monitoring device it was being used to share thoughts on what should best be done next (ibid, p.111). It had, in fact, extended and empowered the links between the various communities of practice – research, development, operations, and management – working within the organization (ibid, p.113). In this respect, it might be said to disprove Focault's prognosis that 'knowledge' always empowers the already powerful (Focault, in McKinlay, 2000, p.107).

In the effort to reduce costs, most companies have sought to reduce the time from discovery to launch. One way in which this can be achieved is by adopting 'rugby team' approaches, whereby the various development activities are run in parallel (Ray and Little, Chapter 2, Section 2.3.2, page 69). Whilst not always feasible in pharmaceutical development, in the case of Company-D, this means designing the manufacturing facility in parallel with the clinical trial. Referred to as 'Fast Tracking' drug development, this process ensures that manufacturing processing problems are solved during clinical trial production, rather than at the later stage during the facility start-up. It also ensures the equivalence of the drug at the clinical and final supply stages by removing any differences in product quality that might be caused by manufacturing scale-up. Since marketed drugs in the UK have to be materially the same as and manufactured in the same way that clinical trial material is produced, this parallel development reduces the time delays that might occur if manufacturing scale-up is initiated after clinical approval and then incurs

unforeseen problems. It does, however, mean that the costs of process design and engineering are introduced before final product approval, thus introducing additional risks into the process. The solution according to Company-D is to manage those risks (Company-D, p.9). Fast tracking is not just about speed; it is also about recognizing what can be done differently. In addition, it is about time-based risk review and planning in all project areas, and about all functions working together as one team. Overall, it is about the 'benefits of having a more robust process and greater product experience within the project supply chain' (Company-D, p.12).

5.3.3 Project Termination

Projects may be terminated at any stage throughout the research and development processes. In research, termination may occur because the project has been handed over to development – the research stage of the project is 'complete' – although research staff usually retain some association with the project, for example, by acting as 'consultants' to the development team. Termination in research may also occur as the result of the science or technology not fulfilling its promise within a reasonable time scale and, therefore, within its cost limit. Termination in development may be for either scientific or commercial reasons: either the science/technology does not fulfil its early promise (for example, clinical trials show irreparable adverse effects); or the developing product/ process is no longer commercially viable for reasons of cost, projected completion date, competitor actions, etc.

In general, companies use their regular project review meetings (team, management, or board) to re-evaluate projects for continued commercial and technical viability and strategic fit (Appendix 5.3, page A14). Decisions in research are based more upon experience and general progress, whilst decisions in development are based upon progress against formal targets (Company-A-4, p.6). Decisions are ideally by team consensus but with the ultimate decision being taken at the executive management or board level:

> '[Project termination is] ideally by consensus, but ultimately a decision [is made] at executive management / board level, after a careful review of existing data, information, knowledge.' Company-I, p.10

> 'Project teams report through a formal structure to an executive team to monitor milestones and resources, to obtain approval to commence projects and to recommend ending a project if it is not meeting our objectives.' www.company-j-2.com/rd_zone/ 29th November, 2001

Several companies admitted that they had not been particularly good at terminating projects. Projects could often drift on or remain in limbo until a use could be found:

> 'We're not very good at it, because if you look at most of our really big sellers, all of them at some stage have come to the point of, 'Well this doesn't work for what we thought it would and we're going to kill it.' ... There are two key considerations: technical and commercial. It's a very fine line to draw. On the one hand, if you keep plugging away at it ... you've got more chance of actually discovering something ... equally, early attrition ... [of] things that aren't going to become drugs [saves] wasting money. It's a mixture of formal reviews and formal milestones between the team and the governance of experienced senior managers, [plus] serendipity and [available] capacity.' Company-A-4, p.7

> 'Well ... in the business school we did a case on Amgen who, you know, are supposed to be the most successful biotech company in the world. And there's a quote in there from somebody saying they never really get terminated, they sort of drift on at a low level.' Company-G, p.6

Others ensure that projects are terminated:

> 'In the past they would be with great reluctance terminated ... In the present climate it's very hard-nosed ... The data is reviewed. The validity of the approach is checked. Is it working/ going to work? Will it be a marketable product? It's much more objective [now].' Company-B, p.12

> 'It's a very transparent system. If people start spending money out of a budget on something which is not an active project, it will not get signed off. So there's

> no opportunity for people to carry on doing a little bit on the side … And people accept it very well. They know that it's actually a positive thing to kill a project before you spend too much money on it.' Company-H, p.8

It was recognized that termination decisions can be especially painful for the research staff who originate a particular avenue of enquiry. To the extent that development staff are less concerned with the creation of the original idea these staff may find it easier to make a detached assessment of the project's worth in the light of prevailing technical and commercial evaluations.

> 'Particularly in the research side people become very protective of their projects. In development, because there is a high attrition rate in the pharmaceutical industry … because it's not our baby and we haven't invented it, we tend to treat them a little bit more objectively. And certainly if something needs to die, we'll just kill it … And people are generally supportive. It's hard if they've worked on something for four years and suddenly it goes down, but they generally accept it.' Company-H, p.7

> 'Scientists don't like having their favourite project canned … It's a process you have to manage. And I think in a small company it is not that difficult to do … It's not as though there isn't something else that is equally exciting and interesting that they can then latch onto. There's no shortage of ideas to progress.' Company-I, p.16

> 'When teams fold … there are celebrations of what the team achieved. If you think about it, most of our candidates don't get to market, so if we only learnt from our successes, we'd be nowhere.' Company-A-1, p.20

As the above quotations also indicate, termination is embedded within a wider process. It is intertwined with the provision of a supportive environment, providing alternative opportunities, and 'learning from failure' (Leonard-Barton, Chapter 2, Section 2.3.3, page 70). Failure is not necessarily the same as a 'mistake' and, if appropriate lessons are learned, it might provide a stepping-stone to subsequent success.

5.4 Knowledge Processes in UK-Based Pharmaceutical R&D

5.4.1 Research

Knowledge Creation

As indicated in Section 5.3 above, the aim of corporate research is to create something that is different to what has gone before: as Polanyi would say, the search for a 'hidden reality' which we may yet discover (Polanyi, Chapter 3, Section 3.4.4, page 120). Consequently, knowledge creation in research is as much about widening scientific horizons as it is about creating knowledge that may ultimately give the organization an advantage over its competitors, although those horizons will, to a large extent, be guided by the objectives of that organization. At the same time, the knowledge created in pharmaceutical research has the potential to provide benefits to the whole of mankind. So, added to the scientific propensity to share knowledge, there is the moral issue that knowledge should not be kept from others if it may do some good. Consequently, much scientific and technical knowledge is available to and is the subject of extensive debate across a wide community of researchers. The difficulty in research is in knowing, at the beginning of the process, which existing knowledge is important and in what way that existing knowledge will ultimately be used (Scott, Chapter 3, Section 3.2, page 89). Researchers may hypothesize about what will happen, but the actual outcomes of research depend as much upon new experimental results as upon existing scientific theory. Indeed the results may well question existing theory. Knowledge creation in research is therefore essentially a knowledge exploration process. And, the techniques employed in research to acquire, share and apply knowledge reflect this knowledge exploration process.

Table 5.4.1 (below) summarizes these techniques and the following paragraphs describe the application, the acquisition, and the sharing of knowledge within corporate pharmaceutical research.

TABLE 5.4.1: KNOWLEDGE PROCESSES AND TECHNIQUES EMPLOYED IN PHARMACEUTICAL RESEARCH

Knowledge Process	**Technique**	**Major Use**
Knowledge Creation	Exploration	Idea generation, problem solution
Knowledge Application	Intuition	Idea generation, problem evaluation, experimental design
	Experience	Idea selection, problem evaluation, and experimental design
Knowledge Acquisition	Peer reviewed literature searches	Idea generation and problem solution
	Patent searches	Project selection and design
	Database searches	Project design and problem solution
	Buying or hiring-in expertise	Establishing new technical ventures
Knowledge Sharing	Personal networking	Idea generation, problem solution, and the advancement of science and technology
	Multi-science-based project teams	Project design, and problem solution

Knowledge Application

Knowledge application in research relies upon individual intuition as well as upon prior experience. What work is undertaken may also be to some extent the result of 'trial and error' – let us try something and evaluate and understand the outcome – although even in

this case it might be argued that intuition will determine what is first undertaken: certainly in a corporate context there is simply not the time to try anything and everything. Importantly, what might be useful in one research context will not necessarily be useful in another (Hull, 2000, p.62). In research, it is not possible to write down a procedure or learn a skill that can then *necessarily* be applied in the same way at a later date. What can be learnt from research stems from the outcome of that research: to what extent does the research project fulfil expectations and do those expectations indicate that a viable product might follow? These are obviously crucial issues from a commercial perspective, but they are not necessarily useful for determining how the next research project should be undertaken. Although projected research outcomes and faith in their commercial value might filter the fruits of creativity, they do not tell the individual researcher *how to be creative* (Section 5.3.2, page 167). And the personal judgement that suggests, to the researcher, the way to proceed in any one instance will differ from one individual to the next and from one project to the next. It will also change as the project progresses, since it changes as new knowledge is created within the organization and within the wider community. As pointed out by one interviewee, this does sometimes mean that when innovation is the object, as in research, the knowledge and lessons of the past are not always thought to be important even when they may be so:

> 'I think there is a ridiculous amount of freedom in the way [research] approaches things … Perhaps that's required because you are expecting people to be essentially creative. But it certainly is another potential barrier to knowledge transfer and so on … Perhaps it would be a lot better for all concerned if we spent a little bit of time looking at what we were going to be doing and what other people have done, rather than just say we're going to change the world and do this again. That's what we historically probably have not been doing, consciously pulling that off.' Company-A-2, p.11

This should not, however, be taken as an argument for or against the 'path dependency' of knowledge (Chapter 2, Section 2.2.4, page 27), since path-dependency was not generally

thought to be a problem in pharmaceutical research (or development). Although most interviewees recognized that existing ways of working might conceivably blind them to new ways of working, they felt that the scientific training of their research (and development) staff was such that existing knowledge was not a hindrance to knowledge interpretation or application, since the factual evaluation of data would overcome too much reliance on existing assumptions:

> 'The whole process of drug discovery is one which requires the assessment of experiments that have gone before as well as those that are new ... Sometimes current opinion will suggest that a particular outcome will result or something cannot be done, but as long as that is an opinion then it is nothing more than an opinion. If you can say that you can't do that and here is the objective information, then it is not an opinion, it becomes factual. You may have overlooked something but it's not an opinion any longer. So in that respect, I think factual evaluation of data gets around the old data being used wrongly. In that respect I don't think it's a hindrance.' Adapted from Company-B, p.20

> 'I think people will come to particular problems with their own baggage … They will be experienced research scientists and will know what Fred Bloggs did in 1992 … and so there is a knowledge set that they rely on … [Yet], we have had examples where guys have said, "I want to try this," but existing knowledge would suggest it wouldn't work. … And we've said, "That won't work" … And [they have gone] away and sometimes it does work. That's the nature of the business we're in …They have a training that does try and make them think sideways and be creative.' Company-I, p.27

At the same time, most interviewees felt that bringing in new knowledge from external sources – in the form of informal knowledge networking, formal collaborations, and hiring-in expertise – could add a new dimension or a new way of thinking (Liyanage *et al,* Chapter 2, Section 2.2.4, page 29) that could lead to revolutionary products or processes that might otherwise not have been thought of (Company-C, p.7).

Knowledge Acquisition

Even assuming that the researcher has a clear idea of how he/she is to initiate a project, with the diverse and complex nature of the scientific and technical knowledge that exists in the pharmaceutical field it is unlikely that he/she will know everything that is needed to proceed with that project (Chapter 2, Section 2.2.4, page 26). Neither will he/she have the time to learn from scratch what is needed. If knowledge is available elsewhere, then why not use it? 'Not invented here' was not thought to be a problem in pharmaceutical research, and knowledge acquisition was said to be of significant importance to all researchers, whether they are pharmaceutical, biopharmaceutical, or biotechnology based. Indeed, it is part of 'due diligence feasibility in both research and development in order to understand what is possible and what might be possible (Appendix 5.5, page A20). Since the knowledge that is deemed relevant at any one time may come from any quarter (Appendix 5.3, page A11), a flexible approach to knowledge acquisition is needed. It is important to have access to a range of knowledge sources and to keep a range of knowledge channels open.

Access to the latest scientific papers is particularly important for increasing the understanding to the individual of the disciplinary status quo (Mansfield, Chapter 2, Section 2.3.1, page 51). This, in turn, may lead to new ideas or solutions for existing problems. Abstracting services for such sources are increasingly available over the Internet, although, as pointed out by one interviewee, it is not always possible to determine whether a scientific paper is or is not relevant to one's own work until it has been read. If payment for the service is high, this can restrict the knowledge accessed by the company (Company-G, p.12).

Patents and patent applications also provide some scientific information, although this may mean that a preferred research approach may no longer be commercially viable. They also provide commercial information regarding a competitor's existing and possible future activities (Company-I, p.26). Most of the larger companies have library support services that assist their research (and development) staff in making literature and patent searches (Appendix 5.5, page A20).

Scientific databases can be useful aids in problem solving. For example, compound databases provide information on chemical structures and properties, and hence suggest, to the knowledgeable user, the likely reactivity of a particular material under specific experimental conditions, and, in turn, the likely effect of a final drug product on the living system. Such databases are often company-based, but are frequently open to and accessed by researchers outside the organization. Simulation software goes one step beyond these information databases to actually simulate the chemical reaction or the effect on the body, and might therefore be thought of as knowledge databases (Appendix 5.7, page A29). These tools cannot (yet) replace actual experimentation, since the 'knowledge' they contain is far from complete, but they can give an indication of which chemical route might offer the best approach for the synthesis of a particular drug.

One way that companies can acquire knowledge directly is by hiring-in knowledgeable employees (Allen, Chapter 2, Section 2.3.1, page 59). Companies tend to do this when they are moving into new areas of research. They will employ an expert in the new field and then grow their own people around that expert (Appendix 5.5, page A20).

> 'We would positively recruit to get that expertise, because you can grow it in-house, but if someone already has the experience you've got a flying start ... We would ... recruit someone with the knowledge and experience that we need to set up a group and then we would grow the group.' Company-B, p.17

When the amount and type of work varies, companies may use contract research organizations for similar purposes. Relationships with contractors can be long term, especially when the contractor has expertise in an area of particular interest, and in this event a considerable understanding may develop between the internal and external staff involved about the knowledge they each hold and their various ways of working (Company-H, p.10).

Knowledge may also be acquired as each individual networks with others, both within and external to the organization. However, since such activities are more normally thought of as ways of sharing knowledge they are described in the following subsection.

Knowledge Sharing

In the initial stages of research, knowledge sharing is overwhelmingly a result of the informal knowledge networking activities that occur between industrial and academic scientists, essentially on an individual rather than a company basis (Appendix 5.7, page A23). These networks would appear to resemble the social circles recognized by Crane (Chapter 2, Section 2.3.1, page 54):

> 'Informal knowledge networking in the scientific disciplines is widespread and vital and crosses organizational boundaries. Networking is part of the scientific process, part of the quest for the scientific truth.' (Company-B, p.22)
>
> 'There is a culture of collaboration and sharing; ideas, information and knowledge are exchanged, as is traditional in the wider scientific community.' (Company-A-1, p.19)

Most interviewees suggested that their researchers tend to keep certain 'community of practice' networks active, whatever the work they are doing, in order to keep abreast of

new developments within their principal discipline (Company-G, p.21; Company-B, p.22; Company-H, p.14; Company-I, p.31). However, they will also form new networks as and when the work requires them to do so (Company-G, p.16; Company-H, p.12).

Most companies do recognize the need for their R&D staff to share basic scientific and technical information, and the knowledge behind that information, outside their organizational boundaries, and they do encourage, or at least accept, these informal knowledge networking practices. They recognize that to progress their work further researchers need to bounce their ideas off each other. They also recognize that in many instances the people with the experience and knowledge to appreciate and expand upon those ideas are external to the organization (Company-H, p.15). Several interviewees also referred to 'serendipity' and the importance of being in the right place to gain the right knowledge at the right time (Company-I, p.28; Company-H, p.5; Company-A-2, p.9).

Attendance at conferences (and the informal meetings that invariably occur before and after conference sessions) is therefore generally encouraged to enable network building. Most (but not all) companies also encourage their staff to give presentations or publicize non-sensitive material: it is part of the reward system. They recognize that even industrial scientists are motivated to some extent by the need to be revered by their scientific peer group:

> 'To some extent scientists are differently motivated from other people … There goal in life is not necessarily to promote the company's activities, it is more to be seen as important by their own peer group. So going to conferences and getting publications and that kind of networking, they see that as their community rather than the company.' Company-G, p.21

> 'Scientists do like to have recognition and they do like to talk about their work at conferences and so forth … People who work in this industry want to be recognized as experts, and the way to do that is through publications, through presentations and so forth.' Company-A-4, p.3

And, not only can such activities build the reputation of the researcher, they can also build the reputation of the company in turn (Company-G, p.23).

Accepting that reciprocity is part of the knowledge sharing process (Brown and Duguid. Chapter 2, Section 2.3.1, page 54), companies trust their staff to, or at least hope that their staff will, consider the commercial implications of the knowledge being shared. Some also take a pragmatic view, recognizing that, come what may, knowledge sharing will occur; that knowledge may be gained as much as, if not more than, is lost; and that in a rapidly changing environment the value of the knowledge exchanged is in any case reduced to zero within a very short time:

> 'So it is a fine balance between sending people off to conferences so they can learn about what everyone else is doing and [everyone else] finding out what we're doing at the same time.' Company-A-4, p.4

> 'There is a tension between the commercial needs for secrecy and the academic world in which information is supposed to be freely available. So when they go to conferences … they … have to tread quite a fine line … I always think, if there's one of your scientists and there's a hundred other people does that mean you're going to learn a hundred times more stuff than you actually give out? Maybe!' Company-G, p.21

> 'I think …most of the information people are going to tell each other has probably, as a currency, lost its value within six months.' Company-I, p.33

Several interviewees suggested that informal knowledge networks can influence the research that companies undertake, since not only are they a source of ideas that may be novel to the company (Company-B, p.24; Company-C, p.9), but they may also influence the knowledge acquired by the individual worker (Company-B, p.25) and thus the work carried out by that worker.

Informal research (and development) networks can also provide routes to commercial networks:

> 'Often you can perceive that you've got a particular product/ opportunity that would be ideal [for another company], but you … haven't established a proper network into that organization to know who is the right person to target. But often you suddenly discover that you know a young research scientist … and his mate … has just joined the company you're interested in … And often that route opens the door to get you into who you should talk to, and that's been successful on more than one occasion.' Company-I, p.32

In general, interviewees felt that the new communications technologies had enabled faster and more time friendly internal and external networking in both research and development (Rothwell (1992), Ahmed (1998), Chapter 2, Section 2.2.5, page 32), but had not significantly altered the networking patterns between the various groups. Staff were said to now email each other rather than talk to one another, even when they work in adjacent offices (Company-H, p.17). However, the new technologies may have increased networking throughout the company as a whole. For example, in at least one company, staff now copy emails to their managers where telephone conversations would not, formerly, have been recorded or reported. The manager is now part of the network and, thus, has a better idea of what is actually happening (Company-H, p.18). Although not specifically questioned, the impression given was that, in general, these actions were not political manoeuvrings on the part of the researchers to curry favour with their bosses (Hayes and Walsham, 2000, p.79), but were genuine attempts to diffuse the knowledge thought necessary to all concerned for future decision making. Perhaps, in this instance, the manager was included in what was deemed to be a 'safe enclave': a shared social space where researchers' underlying views could be expressed freely, allowing for discussion and reflection on the different ways of working (ibid, p.83). A more cynical view, although not the one taken by the present author, might be that researchers were merely covering themselves against future problems. While perceptions about the significance of networks vary, Table 5.4.2 (next page) summarizes interviewees' assessments of the relative importance of the more frequently used research networks.

TABLE 5.4.2: NETWORKS SUPPORTING PHARMACEUTICAL RESEARCH

Network type	Relative Importance
Internal	Variable. Increasing as the research progresses.
Community of Practice	High. Important for idea generation, building and consolidation, and generally for scientific and technical knowledge sharing, building and advancement.
Customer	High. The aim is to meet the unmet medical needs of the patient.
Supplier	Low.
University/ Research Institute	High. They are a major source of ideas for innovative projects and of compounds for drug development. They also support PhD studentships.
Companies in related fields	High. The research in pharmaceutical companies is very highly influenced by what is happening in the biotechnology fields and vice versa.
Government	Generally low, although National Health Organizations may influence some research activities.
Other	The World Health Organization and Opinion Leaders can influence the work undertaken. Competitors' actions are also important.

Although knowledge creation in pharmaceutical research is initially an individual activity, in the larger companies it soon becomes a disciplinary and later a multidisciplinary, if not transdisciplinary, activity as scientists in one discipline begin to work with scientists in a range of other disciplines (Section 5.3.2, page 168):

> 'The purpose of those [multidisciplinary] project teams is to head towards more specific biological activity, which means … understanding how the chemistry interacts with the biology … So the chemist might say, "Here's my chemical route to make that compound." And the biologist may say, "And here's the biochemical pathway that applies." But they have to come together, because if they don't there is no point in trying to rationally design the next compound, to know why this worked or the reason it didn't.' Company-B, p.28

Knowledge sharing through the auspices of team working therefore plays a part in the later stages of research, with review meetings serving as the forum for the introduction of and discussion about the more general scientific and technical advances of interest.

External collaborations do occur at the research stage but these generally take the form of 'blue skies' research undertaken by research institutes or biotechnology companies, in both instances usually for pharmaceutical companies. They are for work that cannot be carried out within the pharmaceutical company due to either commercial pressures or perhaps due to insufficient in-house specialist knowledge, and, as such, they are essentially knowledge 'acquisitions' by the pharmaceutical company for payment of a 'fee'. Some knowledge sharing may occur between company and academic researchers during these collaborations, but in most cases contact usually only becomes important at the development stage.

Principal Knowledge Types, Processes, and Techniques used in Research

With reference to Chapter 2, Section 2.2.6, Table 2.2.1 (page 34), the types of knowledge used during research activities can be summarized as basic scientific and technical knowledge with some design and manufacturing knowledge. The major knowledge processes may be summarized as scientific and technical knowledge creation through exploration and experimentation, based mainly upon knowledge acquisition and sharing through literature searching and informal community of practice networking. That is, the knowledge and knowledge processes mainly associated with first generation R&D and Mode 1 working. However, in order to produce a 'prototype' product some transdisciplinary knowledge application is also necessary.

5.4.2 Pharmaceutical Development

Knowledge Creation

Section 5.3 has shown us that development is about applying the results of research (either internal or external to the organization) in order to produce a new product or process that can be used or sold for financial gain (Jewkes *et al,* Chapter 2, Section 2.3.2, page 64). It is about exploiting existing knowledge to produce new knowledge. And, it is about knowledge production in the context of application (Gibbons *et al,* Chapter 3, Section 3.4.1, page 103). Developers are trained in the same scientific and technical disciplines as researchers and they bring this knowledge to bear on the work they undertake. They do, however, use this knowledge in a more applied sense, looking to mould the research product or process into something that will meet the stringent requirements needed for regulatory approval. To some extent, the work of development is therefore determined by reference to standard procedures (Jewkes *et al,* Chapter 2, Section 2.3.2, page 64), although it is also about modifying these procedures when they are no longer appropriate. It is also about producing a product that can be manufactured efficiently and effectively and to strictly controlled quality requirements. Development thus also relies on the knowledge associated with product and process design. In addition, development is about matching the properties of the product or process to the needs of the business, and about achieving this match within commercially sensitive cost and time scales (Jewkes *et al,* Chapter 2, Section 2.3.2, page 64). Commercial knowledge is an integral factor in deciding development activities; in research it is used more for guidance. These requirements mean that the acquisition, sharing and subsequent application of existing knowledge are also important knowledge processes in pharmaceutical

development, but they also mean that the techniques employed in development differ significantly from those used in research (Table 5.4.3, below).

TABLE 5.4.3: KNOWLEDGE PROCESSES AND TECHNIQUES EMPLOYED IN PHARMACEUTICAL DEVELOPMENT

Knowledge Process	Technique	Major Use
Knowledge Creation	Exploitation	Idea generation, problem solution
Knowledge Application	Project team working with due regard to standard procedures and regulations	Project selection, design, implementation, and evaluation
Knowledge Acquisition	Individual networking	Accessing procedural knowledge for regulatory approval
	Licensing	Product and process acquisition, developing product expertise, gaining financial resources, reducing development time
Knowledge Sharing	Team working	Project implementation
	Knowledge networking	Idea generation, problem solving, and the advancement of science and technology
	Formal collaboration	Resource (financial, scientific, and technical, and human) acquisition, idea generation (technical and commercial)
	Company reporting	To review and focus activities

Knowledge Application

The need for continued scientific, technical, and commercial input means that knowledge application in development is invariably a multifunctional team-based activity (Section 5.3.2, page 168), with team membership typically including staff from regulatory, manufacturing, and marketing departments, in addition to the various scientific and

technical units. When formed as the result of collaborative ventures, teams will also contain members from outside the organization. In all instances, team selection is based upon the capabilities and competencies needed for the task in hand (Kanter (1983), Best (1990), Leonard-Barton (1995), Chapter 2, Section 2.3.2, page 64).

Since the development process follows a fairly structured and regulated route, what is required in one instance is often the same as what is required in another instance. Projects can therefore be defined, designed, scheduled, implemented, monitored, and controlled. Consequently, they are amenable to the standard practices associated with traditional management approaches (Section 5.3.2, page 171).

The procedures employed may be discipline, task, or project-related. Scientific and technical databases may contain information regarding discipline-based practices which may help in project implementation. Internal company or local authority reports are often available outlining the steps for obtaining regulatory approval. Development updates and end-of-project review meetings are used for consolidating or improving existing practices. Such meetings allow for two-way communication, and hence cater for discussions regarding the applicability of using an existing approach in a new context: the judgement call is informed. They may also highlight problems encountered, and enable solutions to be suggested. Incident reports, case reports and 'lessons learnt' databases pinpoint project problems encountered and overcome in a particular context, but their applicability in another context may be unknown: the judgement call is perhaps less informed.

Several interviewees felt that their companies had not always been particularly effective in using much of the experience that they had available to them:

> [The company] hires people, like myself, who've got very relevant experience in the industry or in similar industries … and we're saying, 'Well from my experience in my past company you do this, this, and the other.' And that is possibly not acted upon as often as it ought to be.' Company-G, p.15

One company was tackling this problem by promoting 'action-based learning' techniques.

An example given was that of cross-team participation: the team that has recently completed a project, actively shares its knowledge and ways of working by participating with a new team that is in the early stages of a project (Company-A-1, p.14). It was noted that although the members of the old team were happy to share their thoughts and ideas with the new team, there was a degree of reluctance on the part of the new team, particularly the scientific members, to learn from the old. This was attributed, in part, to the need to see the relevance of what had been done before, and then to apply the lessons learnt:

> 'It's not so much a problem getting people who have just completed to share their knowledge, they are usually very happy to share it. It's more a problem editing it … and making sure that it's relevant … The biggest problem I find is getting people to reflect on that data, turn it into information that they can use and then behave differently as a result of it … Sometimes it's because they have a real belief that their team or their compound is so different to this other one that it couldn't possibly apply to them. Sometimes it's difficult because they don't have time to apply it; they're so swept along by the whole process. So that to me is where the crunch is, of actually getting people to apply what other people have learnt.' Company-A-3, p.1

It was also thought to be due to the early scientific training of these workers, which emphasized individual questioning and learning by experimentation rather than learning from others:

> 'I think … we employ people [scientists] who are not inclined to learn from other people, they're inclined to learn from their own experience… I think it is absolutely to do with their training. They're taught to not take anything at face value, 'Test it out for myself.' Company-A-3, p.2

But, additionally, it was thought to be due to a degree of scientific arrogance:

> 'But it is also about, 'Well why should I learn from you? I'm different.' Company-A-3, p.2

Once such a process was seen to be useful, it was said to work well (Company-A-1, p.8). However, a problem was voiced about how to get the project team 'learning' back to the technical lines in general. This was thought to be important, first so that others could learn the same lessons, and second so that team members could be recognized and justly rewarded for what they had achieved:

> 'So … we can see compound teams learning but we don't necessarily [see] individuals back in the line learning … What I'm not clear about at the moment is whether there is a drive to do 'learnings' back in the line, if you like in the professional line. I think that's very important, and until we start doing that you don't get managers absorbing 'learnings', therefore you don't get people being rewarded for having learnt and put things into practice.' Company-A-3, p.3

Knowledge Acquisition

As implied in the previous subsection, the success of a development project is dependent upon the effective synthesis of commercial and technical information. For example, raw material, product, and manufacturing costs; health and safety and material handling requirements; regulatory issues; as well as market needs will need to be known (and met). Knowledge of competitor clinical trials may also indicate whether a particular development approach is justified or should be abandoned for either technical or commercial reasons.

Individual knowledge networking was particularly important in helping staff to develop an understanding of what would be expected for future regulatory acceptance:

> 'I did some interviews … with some people who were going to leave the company for retirement … Something that a couple of people who had been here

> a long time were very concerned about was the relationships that they'd built up with people in government positions, in hospitals, in wherever, [that meant that] … there was a general understanding of what [was] required to do a clinical draft or whatever, so that they could very quickly … get those sorts of things done … those sorts of relationships were [going to be] lost, and would take another fifteen years to get back.' Company-A-4, p.4

In-licensing agreements are used extensively to gain access to both technology and products (Appendix 5.5, page A20; Chapter 2, Section 2.3.1, page 52). Pharmaceutical companies in-license technology from the newer biotechnology companies to increase their knowledge about the latest analytical methods and techniques, and they in-license drugs from biopharmaceutical and other pharmaceutical companies in order to gain competitor knowledge and fill or augment their product pipelines. Biotechnology companies in-license technology from academic research centres and other biotechnology companies to gain additional technical knowledge, and they in-license drug product from pharmaceutical companies in order to test their own technologies. Biopharmaceutical companies in-license drugs and technology from research institutes and other companies to build their strengths in drug discovery and rapid product development. Indeed one of the companies in this sector undertakes all of its development work using in-licensed products (Appendix 5.5, page A20). In contrast to Dickson and Hadjimanolis' findings (Chapter 2, Section 2.3.1, page 52), the exclusive use of licensors does not appear to have had a negative affect on the wider learning and accumulation of expertise in this particular organization. The difference, perhaps, is that knowledge (as well as information) is being acquired. In agreement with the findings of Quintas and Brauner on outsourcing activities (Chapter 2, Section 2.3.1, page 52), this particular company has perhaps retained the capability to understand and assimilate the external knowledge and combine it with its internal resources and capabilities. This is something that is perhaps easier to achieve when scientific knowledge is involved, as in this instance. Whether this particular approach

would continue to be viable was, however, questioned on the grounds that it is now much easier for academics to obtain venture capital to set up their own companies and develop promising candidate drugs themselves (Company-G, p.14).

One company's in-licensing agreement is another company's out-licensing agreement. And, whilst in-licensing may bring a dependency upon others for new knowledge, out-licensing offers a company the chance to use its knowledge on a wider basis and in different ways, often for direct financial gain. What is interesting in the pharmaceutical industry is that many companies participate in both activities to roughly equal degrees. So, like in-licensing, out-licensing is also a major activity for all of the companies in this study (respectively, Appendix 5.5, page A20, Appendix 5.6, page A22). The use of in-licensing and out-licensing together means that, at the development stage, rather than the possibility of one company becoming dependent upon others for new knowledge acquisition, or one company exploiting its knowledge to others for financial gain, all companies within the pharmaceutical industry are to a degree dependent upon each other for knowledge acquisition and its subsequent application.

The larger pharmaceutical companies usually have a central function looking into in-licensing and out-licensing opportunities. They usually (although not always) out-license non-core products and technology. Out-licensing provides additional revenues for internal research and development, and, in the case of smaller companies, may provide sales access to new geographic markets. Cross-licensing of products between major pharmaceutical companies also occurs so that they can each effectively avoid monopoly situations and subsequent government interference in their operations.

Out-licensing is particularly important for the smaller biopharmaceutical companies. These companies, at least in the early years, do not have the financial resources to pay for the huge costs of drug development and neither do they have the marketing and sales forces needed for final product launch. They therefore rely on out-licensing their intermediate stage product (researched to 'proof of concept') to large pharmaceutical companies to gain financial resources for further in-house R&D. Payment to the biopharmaceutical company is typically in the form of either (a) an annual licence payment plus a percentage on final sales, or (b) total payment for the continued development of the product to launch. Option (b) is often chosen initially, although access to venture capital can negate the need for this approach and consequently favour option (a). As the biopharmaceutical company becomes 'cash' rich it tends to opt increasingly for option (a), until eventually it has sufficient resources to develop products entirely in-house. In so doing, the company removes the risks associated with R&D from the eventual buyer and can thus ask for a higher premium on sales. A number of US biopharmaceutical companies have pursued this strategy very effectively and now have the resources to compete with the traditional pharmaceutical companies that have often paid for their early development.

Out-licensing is also a necessity for most biotechnology companies. These companies have a (new) technology that is an aid to drug research and development, but their knowledge of particular drug treatments and drug effects is often minimal. Neither do they necessarily see drug development as part of their business remit, at least when they are initially founded. They need both the finances and the knowledge of the pharmaceutical companies to fully exploit their technology. At the same time, pharmaceutical companies are always looking for ways in which they can reduce the time and costs of drug R&D.

A technology that offers such advantages is obviously worthy of consideration. These alliances between biotechnology companies and pharmaceutical companies are said to be extensive and usually successful. Perhaps the major reason for their success is that it is in the interests of both parties that the technologies are developed as far as may be possible. However, in time, biotechnology companies may themselves decide to move into drug development. There will then be a move from a model of 'mutual collaboration' to one of 'competition'. Who will be the winners and who the losers, or can all companies remain winners? The pharmaceutical companies have an edge in that they have the resources and abilities to access a whole range of technologies. The biotechnology companies have an edge in that they can concentrate on developing one or perhaps several technologies to gain further advantages. The question is, 'For how long will those technologies remain the technologies of choice?'

Knowledge Sharing

In development, the sharing of project-related knowledge is through the auspices of team working, whether or not these teams are formed as the result of a formal collaborative venture (Appendix 5.8, page A30; and page 189 above). In the larger companies, manuals may also exist for training new starters in business awareness, and verbal briefings may provide updates on company-wide issues. Company intranets are common to all organizations, but their usage can vary – perhaps in relation to the particular 'politics' of the situation (Hayes and Walsham, 2000, p.83; Newell *et al,* 2000, p.90). Key business priorities are, however, generally cascaded throughout organizations to ensure a unified focus and purpose to the work being undertaken (Appendix 5.7, page A26).

Working in multidisciplinary and multifunctional project teams was said to enhance knowledge continuity between research, development and the commercial activities, and increase the common understanding of what is required from all workers (Kanter (1983), Best (1990), Leonard-Barton (1995), Chapter 2, Section 2.3.2, page 64). Task-related difficulties, possible solutions, and the likely business implications are shared within the team as they arise and do not have to await the advent of the next review meeting. Delays in operational decisions are thus minimized (Appendix 5.7, page A26).

Working together in multifunctional teams also offers opportunities for team members to begin to understand and appreciate the workings of other departments. However, since development teams in the UK pharmaceutical industry consist of people who bring their own particular skills (functional and discipline-based) to the process, the extent to which these team members share the same 'language' is likely to be severely restricted compared to their multi-skilled Japanese counterparts (Ray and Little, Chapter 2, Section 2.3.2, page 69). In addition, the fact that development teams are usually relatively short-lived (although some in the pharmaceutical industry may last for 8-10 years) further reduces the likelihood of any in-depth shared understanding. On the other hand, the fact that teams are dissolved and new teams are formed with different members means that the diversity of knowledge that is brought into the process increases and with this may come the chance of some unique solutions.

Knowledge networking does occur in development but not to the same degree as in research. Knowledge networks are important for individual development scientists and for much the same reasons as for research scientists – to expand their scientific and technical knowledge – but the 'rules of engagement' differ. Owing to the commercially sensitive

nature of development, external knowledge networking in development is, in line with Myers and Marquis' (1969) and Oliver and Liebeskind's (1997/98) findings (Chapter 2, Section 2.3.2, page 67), restricted to matters that are more general:

> 'As things progress … into development, people become much more secretive … I'll go along to a meeting and I'll talk to my opposite number and be very friendly, but we wouldn't dream of giving each other anything that could be construed as proprietary information.' Company-H, p.14

The relative importance of the networks used to support development is suggested in Table 5.4.4 (below). As mentioned in the preceding subsection (page 192), networks with the regulatory authorities are very useful in gaining an understanding of what is currently required for product licensing. And, long-term networks between company employees and the regulators, built upon mutual trust and shared understanding, can aid in the acceptance

TABLE 5.4.4: NETWORKS SUPPORTING PHARMACEUTICAL DEVELOPMENT

Network type	**Relative Importance**
Internal	High within project teams. Moderate across project teams.
Community of Practice	High. Important for problem solving and for idea generation, building and consolidation. Fairly important for scientific and technical knowledge acquisition and sharing.
Customer	High. Drug trials are dependent upon volunteer patients.
Supplier	Low, although they can act as advisors to projects.
University/ Research Institute	Generally high. Support is both formal through agreed contracts and informal through old pals' networks.
Companies in related fields	High between pharmaceutical and biotechnology organizations, and between these organizations and clinical research organizations.
Government	High from a regulatory perspective. Limited as regards the provision of grants.
Other	Trade Associations help build industry consensus. Business Associations may also promote scientific and technical development initiatives. Partner organizations can profoundly affect development progress by providing knowledge, resources, funds, etc.

of new procedures (by either the organization or the regulatory authority) when these are necessary. On the other hand, networks within Trade Associations help to harmonize industry views about what should be required in the future (Appendix 5.7, page A25). And, Trade Association lobbying enables a more coordinated approach to be taken when existing regulations are seen to be inappropriate by industry members. Knowledge networks in development are therefore closer to those of the technologists described by Allen (Chapter 2, Section 2.3.1, page 58); although the role of technological gatekeeper would appear to have diffused down to the individual scientists (Chapter 2, Section 2.3.1, page 60).

Participation in government initiatives to encourage informal knowledge sharing between organizations is limited. Several interviewees felt that many of the technical areas dealt with in pharmaceutical development do not have direct equivalents in other industries. The opportunities for cross-industry learning were therefore minimal. On the commercial side, the pharmaceutical industry in the UK is also different to most other industries in that direct sales and advertising to the consumer is not allowed. Management techniques were thought to be the exception to the rule whereby cross-industry networking might prove helpful (Company-A-4, p.14; Appendix 5.7, page A27). In reality, only one of the companies studied was involved in such a government initiative. Called 'London First', this was described as a 'government quango' which promotes industry and infrastructure in the London area. Mixing chief executives, business managers, academics, industrial scientists, intellectual property advisors, venture capitalists, etc., it was formed to encourage closer collaboration between industry and the London Research Hospitals, to everyone's mutual benefit (Appendix 5.7, page A27). Whilst having no clearly defined

benefits to report, London First was said to be well supported and did provide a degree of scientific cross-fertilization.

Whilst strategic scientific and technical knowledge is rarely shared through external informal knowledge networks during development, it is shared through formal collaborative ventures. Collaborations usually occur between pharmaceutical, biopharmaceutical, or biotechnology development units and universities or other research institutes; and between the development units of pharmaceutical companies and those of either biotechnology or biopharmaceutical companies. Collaborations may also occur between biotechnology companies, who are increasingly combining their technologies to develop new ways of doing things (Appendix 5.8, page A31).

In line with the literature reports (Chapter 2, Section 2.2.4, page 26), the main reasons given for such partnerships were to gain resources, share costs, or generate ideas. They provide the financial and commercial resources needed by younger and smaller companies to enable them to develop their products or processes further. They provide the scientific and technical expertise that is not available in-house (Company-G, p.17). They suggest ideas for novel products that would not have been thought of or made possible by in-house development alone (Company-B, p.21). And, they give older companies access to the latest patented knowledge, which might not necessarily be available to them through any other arrangement (Company-I, p.29). An additional reason mentioned for collaborations with the universities and research institutes was that companies have a vested interest in fostering relations with these institutions, since they ultimately provide the new generations of company scientists and technologists upon which their R&D departments depend (Company-B, p.15).

Collaborations of all types were viewed as bringing benefits to all parties involved, although it was recognized that this was sometimes at the cost of increased complexity of working, some lack of overall control of the process, shared ownership of the outcome, and the possible need for conflict resolution (Appendix 5.8, page A33). Collaborations between academia and industry were said to be particularly prone to conflicts of interest because of the different perspectives employed by the participants. The academic pursuit of scientific excellence is not always necessary for the effective development of a commercial product or process.

Collaborations in the pharmaceutical industry are always formal in nature, that is, they are always agreed by contract. This is because patent rights and technology know-how may ultimately provide the huge sums of money required for continued commercial viability. However, in line with Ray's findings (Chapter 2, Section 2.3.2, page 67), most interviewees felt that once a collaboration was established it was important that all parties to the collaboration should share their knowledge and work as one team without the restriction of bureaucratic controls or the hindrance of 'red-tape' (Appendix 5.8, page A31).

Existing collaborations often suggest ideas for further work. This may result in the existing collaboration being extended or a new collaboration being formed (Company-C, p.8). Successful collaborations may lead to further joint working between the same partner(s), because the expectation is that the new collaboration will also be productive. Alternatively, they may lead to new collaborations with new partners, because eventually the particular expertise brought into the organization by the original partner(s) will become part of the organization's own knowledge base. At that stage, new partners

are sought with different expertise to increase further the pool of in-house knowledge (Company-B, p.23).

The apparent success of collaborations in the pharmaceutical industry would suggest that the companies involved have perhaps struck the right balance between 'renewal and stability' (Kumpe and Bolwijn, Chapter 2, Section 2.2.4, page 28).

As noted in Section 5.3.2 (page 171), project management tools are increasingly being used to share project-related information. By informing others, it is hoped that the relevant knowledge held throughout the organization can be brought to bear at each and every stage of the project (Appendix 5.7, page A29). That is, project management is also viewed as a tool for knowledge sharing, and not simply as a method for control (Burton *et al*, Chapter 2, Section 2.3.2, page 66). By acting as a 'boundary object' (Chapter 2, Section 2.3.2, page 68), project management tools have perhaps replaced any need for dedicated knowledge translators and brokers within the development process.

A number of companies are looking into the use of electronic laboratory notebooks for the sharing of detailed technical information. A current 'sticking point' is that verifiable data entry (a requirement for claiming patents in the USA) is not yet a possibility (Appendix 5.7, page A28). Experts' databases are used to point individual workers to the expertise and skills available within and sometimes external to the organization. Several companies also store project information in the form of 'stories' databases: what was done, why it had been done, what were the lessons learnt, etc. Companies initially attempted to make the 'lessons learnt' sections of these databases context independent. Most now accept that this is difficult, if not impossible, to do, and rely on their trained and

experienced staff to make sense of the lessons of the past and, where appropriate, relate these lessons to the problems of the present. There was a consensus, however, that databases can become unwieldy and considerable resources are needed to keep them up-to-date. There is also the dissatisfaction that in any case databases cannot contain the knowledge, and neither do they usually contain all of the relevant information that is available within the company or that is necessary in order for people to carry out their work activities. And, even when databases do contain valuable lessons, people rarely have the time to make the necessary searches. As a result, some of the larger companies are now attempting to incorporate the latest knowledge and thinking into their day-to-day working practices rather than simply trying to provide 'knowledge' in a database (Company-A-1, p.15). The importance of such an approach is suggested by the fact that some companies are employing teams of people to make this happen:

> 'Project management do have this big database of lessons … The challenge is in getting it to the people to whom it matters, because these folk are extremely busy.' [Company-A-1, p.15] … 'The remit for ourselves is … to try to mobilize this internal knowledge, primarily working between departments as the glue or the jelly if you like that holds things together.' [Company-A-1, p.1] … 'Do you start by capturing it all, building this big database and let people use it as they see fit? Or do you … [ingrain] it in the day-to-day working practices? … I think, the key thing is action-based learning, action-based knowledge; work with the people who are actually going to make a difference.' Company-A-1, p.6

The process of cross-team participation outlined in the previous subsection on knowledge application (page 191) is an example of such an approach.

Principal Knowledge Types, Processes and Techniques used in Pharmaceutical Development

With reference to Chapter 2, Section 2.2.6, Table 2.2.1 (page 34), the types of knowledge used during development activities can be summarized as basic scientific and technical knowledge, product and process knowledge, design and manufacturing knowledge, commercial knowledge (particularly marketing and legislative knowledge), and team working and project management skills. The major knowledge processes can be summarized as knowledge creation through exploitation and adaptation, based upon knowledge application and sharing mainly through team and collaborative working. That is, the knowledge and knowledge processes associated with third and fourth generation R&D and Mode 2 working.

5.5 Conclusion to the Chapter

This chapter has described the approaches, the practices, and the knowledge processes employed within UK-based pharmaceutical R&D, which form the building blocks for the discussion presented in Chapter 6. In so doing, it has, to a degree, confirmed some of the findings of previous researchers. However, it has also demonstrated that overly simple models may do violence to the complex processes of pharmaceutical research and pharmaceutical development. Although the chapter has confirmed the importance of business integration (third generation R&D) and external collaboration (fourth generation R&D) as corporate R&D approaches, it has noted that such approaches occur during pharmaceutical *development*. In contrast, pharmaceutical *research* continues to reflect a science/technology pushed (first generation R&D) approach. Thus, what would seem to be reality at the corporate level is not necessarily so at the task level, a result that is perhaps not unexpected when we consider the different natures of research and development: research is about the exploration for something new, whereas development is about the modification or adaptation of something that already exists.

Perhaps, most importantly, this chapter has detailed the way in which the practices of research differ from the practices of development. In research, project initiation is dependent upon the thoughts and ideas that originate from in-house technical or commercial teams, often influenced by leading-edge university research, and which may or may not fit with existing corporate strategy. Project management is flexible and non-bureaucratic, often discipline-based, and individualistic in nature. Project termination is by consensus based upon expert opinion. In contrast, in development, project initiation results from either in-house or external work that has passed the requirements of initial clinical

trials, and which is deemed both commercially and technically viable. Project management is traditional in the sense that projects are defined, designed, scheduled, monitored, reviewed and controlled to ensure costs and timescales remain within predetermined limits. Project teams are multidisciplinary, multifunctional, and often multi-site and multiorganizational, but an essentially transdisciplinary approach is encouraged by giving control of the matrix of workers to specific project managers, rather than allowing control to be determined by either the technical or marketing functions. Project termination is affected by commercial and technical requirements. Again, these different processes can be related to the different natures of research and development.

Whilst pharmaceutical R&D is dependent upon the acquisition, sharing and application of knowledge held throughout and external to the organization, the types of knowledge and the techniques employed to acquire, share and apply that knowledge differ significantly between research and development. Whilst research relies predominantly on scientific and technical knowledge, development requires a synthesis of mainly commercial and technical knowledge. Whilst flexible techniques such as personal networking are used in research for the acquisition and sharing of extra-organizational knowledge, more coordinated methods such as formal collaborative ventures predominate in development. And, whilst knowledge application in research is largely the remit of the individual, knowledge application in development is through the auspices of team working. The knowledge creation process in research is thus fundamentally different to the knowledge creation process in development, and this again can be attributed to the fundamental differences between research and development: research is about the exploration for new knowledge, whereas development is about the exploitation of existing knowledge.

Although knowledge creation in research shows many similarities with Gibbon's *et al's* Mode 1 form of knowledge production – it is discipline based, it is individualistic, it does assume a linear view of science – it was noted that some transdisciplinary knowledge working is also necessary for a research product to reach 'proof of concept' or 'prototype' stage. At the same time, although knowledge creation in development has many similarities with these authors' Mode 2 form of knowledge production – it is carried out in the context of application, it is team-based, it is transdisciplinary – team formation and dissolution is ultimately governed by a management body and not through self-evolution. The Modes of knowledge production along with the knowledge creation models suggested by Nonaka and Takeuchi, Cook and Brown, and Polanyi are discussed further in Chapter 6, which, in addition, elaborates upon the reasons already suggested as to why things are as they are in pharmaceutical research and pharmaceutical development.

6 DISCUSSION

6.1 Introduction

This chapter takes another look at the literature outlined in Chapters 2 and 3 in the light of the findings of the empirical research presented in Chapter 5.

First, Section 6.2 revisits the R&D generations approaches described in Chapter 2, Sections 2.2.1 to 2.2.6, to assess the extent to which UK-based pharmaceutical R&D has evolved, and might be expected to evolve towards the virtual learning systems characteristic of fifth generation R&D. The suggestion is that whilst pharmaceutical development may be expected to retain the business integration and collaborative approaches associated with third and fourth generation R&D, pharmaceutical research should continue to adopt the science/technology push approach of first generation R&D. The move from first to fifth generation R&D is far from being a certainty. And, as noted earlier in Chapter 2 (Section 2.1, page 15), the advent of a new R&D generation does not necessarily replace or negate the existence of former R&D generations.

Second, Section 6.3 discusses the extent to which UK pharmaceutical R&D reflects Gibbons *et al's* modes of knowledge production outlined in Chapter 3, Section 3.3.1. The suggestion is that whilst pharmaceutical development might be described as a 'Coordinated Mode 2 type' activity, pharmaceutical research may be more appropriately termed a 'Transdisciplinary Mode 1 type' activity. Thus, whilst there might appear to be a move

away from the scientific discipline-based Mode 1 approach to the application-based Mode 2 approach, this is not the entire picture.

Third, the chapter revisits the knowledge creation models outlined in Chapter 3, Sections 3.4.2 to 3.4.4, to establish the extent to which these models might be useful in explaining how knowledge is created in UK pharmaceutical R&D. By considering the various activities involved in the research and development processes, Section 6.4 suggests that, whilst the uncritical acceptance of Nonaka and Takeuchi's model of tacit-explicit knowledge conversion raises problems, their model *does* highlight the importance of knowledge sharing, concept generation, knowledge combination, and knowledge acquisition in contemporary corporate R&D. And, whilst the definition of different types of knowledge in Cook and Brown's 'generative dance' between knowledge and knowing is perhaps questionable, their framework nevertheless *does* point to the fact that we use the knowledge available to us at the time to undertake the task in hand. Moreover, whilst Polanyi's model does not talk about organizational knowledge creation as such, it *does* nevertheless point us towards a better understanding of how individual knowledge is created, how individuals learn from others, and thus how knowledge might be created in an organizational setting.

Fourth, Section 6.5 links context with practice to look at the reasons for why things are as they are, and concludes that it is the needs of research that influence the management of research, the knowledge needs of research, and knowledge creation in research, but it is the needs of the organization that influence the management of development, the knowledge needs of development, and ultimately how knowledge is created in development. The

suggestion is that research should be to some extent the master of the organization, whereas the organization should definitely be the master of development.

Fifth, Section 6.6 discusses the implications of the various factors identified by the empirical research as being those most important in managing R&D in the pharmaceutical industry. In so doing, the section highlights the emphasis on commercial viability in development, whilst suggesting the need for a degree of exploration in research, factors which can explain the separation between the activities of research and development, but not of the people involved.

Finally, Section 6.7 poses some questions and draws some conclusions.

6.2 The R&D Generations and Pharmaceutical R&D

In recent years, collaboration in the pharmaceutical industry has been used as an exemplar of fourth generation R&D (see, for example, the work of Liyanage and co-workers, 1999). And, as confirmed by the findings in this study, collaborations do abound in this industry. Collaborations are formed between many players: mature multinational pharmaceutical giants; medium-sized biopharmaceutical companies; medium and small biotechnology companies; universities and other research institutes. And they are formed for the usually quoted reasons: to gain access to the latest scientific and technical knowledge; to gain access to business resources such as financial assistance, marketing knowledge and sales facilities; and to share costs (Chapter 5, Section 5.4.2, page 200). In essence, organizations collaborate to overcome their weaknesses and build upon their strengths. However, this study has also found that collaborations normally occur at the development stage. Although some research may be outsourced to universities or other research organizations, the finding was that corporate research is mostly carried out in-house. It is the outcome of that research (pharmaceutical, biopharmaceutical or biotechnology) that is then developed further through scientific and technical collaboration. It is perhaps therefore more accurate to say that pharmaceutical development is the example of fourth generation 'R&D'. At the same time, and in line with third generation R&D, it is clear that both commercial and technical considerations hold the key to development, since projects will not be undertaken without a clearly defined business advantage and route to commercialization (Chapter 5, Section 5.3.1, page 166).

Despite the fact that pharmaceutical research is still very much built upon the science/technology push philosophy of first generation R&D (Chapter 5, Section 5.3.1, page 163), there are indications that this is increasingly being replaced with a 'business integration' (third generation R&D) approach. Expending money on speculative work that may or may not eventually yield vast returns is possible when companies are able to adequately recoup these costs. It becomes difficult when companies are increasingly called to reduce prices to meet government edicts, or to answer concerns about access to medicines and health care for the most vulnerable members of society (Chapter 5, respectively, Section 5.2.1, page 150; Section 5.2.2, page154). Whether or not a more business oriented approach is a good thing remains to be seen. Competitive innovation, driven by the quest for monopoly profits arising from being first-to-market, is particularly important in the pharmaceutical industry. Promises of such profits are fundamental to the financing of the expensive clinical trials needed for further drug development. In the past, the UK pharmaceutical industry has itself carried out a significant amount of basic scientific research in order to produce more advanced products and thus secure such profits. With the increasing pressure to achieve rapid commercial returns from an increasingly global market, companies might find it more difficult to create 'space' for truly basic research. Although universities and medical research centres might be able to take up the shortfall, transforming promising ideas into prototype pharmaceutical products typically requires significant investment; investment that, politically, may not always be available.

Regulatory harmonization within the European Union adds a further dimension to the costs of developing novel products and the benefits that might accompany their success. Given such high stakes it would seem important that the leading pharmaceutical companies make

every effort to coordinate their assessments of the viability or otherwise of promising R&D programmes. On this account, dealing with sources of invention outside the firm may offer substantial cost savings, but they can also accentuate concerns about trust: the apparent *efficiency* of collaborating with strangers can be overshadowed if these strangers fail to deliver what was agreed, or if they misuse sensitive information.

If fourth generation R&D is a reality in pharmaceutical R&D (or at least in pharmaceutical development), is fifth generation R&D also a reality or could it become so? Viewed from an organizational perspective, there is reason for caution. Although some R&D projects may result from the 'opportunistic alliances' formed during *ad hoc* meetings at conferences, during existing collaborative ventures, or simply during the normal course of research or development work (Chapter 2, Section 2.2.5, page 29), many more projects are the result of the purposeful search for and managed solutions to specific business objectives (Chapter 5, Section 5.3.1, page 163). If, however, we consider the informal networking activities between individual R&D workers, particularly at the research stage, then fifth generation R&D would appear to have existed for many years, since these activities *do* depend upon the mutual respect among R&D personnel distributed among a number of distinct operating entities, and, within these networks, there *is* the need and willingness to continuously learn from each other to create new knowledge as a way of adding value to the entire system (Chapter 5, Section 5.4.1, page 183). Repeat transactions in these informal networks can mean that participants, who come to know each other well, are able to trust each other's judgement, and make effective use of ideas that arise from elsewhere (thereby circumventing the negative implications associated with the 'not invented here' syndrome).

In line with Rogers' fifth generation R&D (Chapter 2, Section 2.2.5, page 30), pharmaceutical management practices *would* appear to be fluid and flexible, especially in research, and management systems *would* appear to be collaborative (Chapter 5, Section 5.3.2, page 167), with R&D now being just one part of a networked innovation system (Chapter 5, Section 5.4.2, page 202). However, whether R&D managers really think about their work in terms of 'knowledge working' to include the 'optimization and monitoring of knowledge flows' is perhaps questionable. Certainly, knowledge sharing is deemed extremely important and is actively encouraged, but knowledge optimization and monitoring implies a degree of control that might owe more to 'industrial age' factory work than twenty-first century 'knowledge work'. In addition, the assessment of performance in terms of intellectual assets is perhaps counter-productive in a team-based environment. Performance assessment in terms of the ability to create and apply new ideas in the market place is perhaps also inappropriate when failure rates are as high as they are in the pharmaceutical industry. In fact, all companies in this study recognized the need to support genuine failure, that is, failure that has resulted because of the unexpected need for further knowledge, or because of the unforeseen outcomes of the experimental search for new knowledge. Certainly the major shifts that Rogers notes (Chapter 2, Section 2.2.5, page 30) *are* happening in practice, but whether these will ultimately result in the collaborative learning networks exactly as envisaged in her conception of fifth generation R&D is doubtful.

Pharmaceutical R&D practices also illustrate many of Ahmed's suggested fifth generation 'success factors' (Chapter 2, Section 2.2.5, page 32). For example, the importance that Ahmed attaches to innovation and discovery continues to be a distinguishing feature of leading innovators in the pharmaceutical sector. Similarly, his idea that fifth generation

R&D should encourage the internal sharing and processing of ideas *has* become increasingly important. However, Ahmed's vision of a culture of 'equals' raises questions about what is meant by *equal*. Innovation turns on the capacity of individuals to imagine a difference, and the extent to which the organization is able to 'make a difference'; an undue focus on equality can distract attention from the relationship between diversity and the power to innovate. Also, Ahmed's suggestion that fifth generation R&D will result naturally from the increased utilization of the new telecommunications technologies (Chapter 2, Section 2.2.5, page 32) is not born out by this present study. The findings herein suggest that although these technologies have aided communications between R&D workers and others, they have not *substantially* increased or altered the communication linkages or the way in which collaborative ventures develop (Chapter 5, Section 5.4.1, page 185). There is a fundamental difference between advances in electronic communication, as a tool for communicating, and the incentive to use that tool. In addition, in line with Rothwell's approach (Chapter 2, Section 2.2.5, page 30), formal collaborations are very much dependent upon a 'managed' approach towards meeting the organization's objectives. R&D strategies are now more planned than emergent, and in an industry that is increasingly under pressure to reduce costs it is hard to see that this will change. For the near future, fifth generation R&D practices, at least in the UK pharmaceutical industry, are likely to be limited to the informal workings between individual R&D employees rather than between different organizational entities.

Another reason why virtual R&D laboratories may not be appropriate to an organization's need for flexibility and economy stems from the shared understanding that is inherent among organizational *insiders*: where members of a single organization share a history of working closely together, it is often relatively easy to understand the context in which an

idea is to be used or a problem is to be solved, and the constraints on what can be undertaken and the limitations to what can be achieved. When the work to be undertaken involves participants from different organizations, the background to the problem may be understood in different ways, the constraints imposed may differ, and the expected outcomes may vary significantly. In consequence, there is a 'time cost' in building the required shared understandings needed for effective collaborative ventures, which may outweigh any of the advantages gained. This was noted to be particularly the case in industry–university collaborations (Chapter 5, Section 5.4.2, page 201).

6.3 The Modes of Knowledge Production in Pharmaceutical R&D

Research

In Chapter 5, it was suggested that knowledge creation in pharmaceutical research is essentially Mode 1 in nature: it *is* often carried out by a lone individual working from the basis of a particular scientific discipline; it *does* involve the production of new 'scientific' knowledge; and it *does* assume a linear view of science and innovation to the extent that new ideas are transferred to development teams for exploitation. Hence, there *would* appear to be a separation between the producers and consumers of knowledge. But it was also implied that it was not that simple (Chapter 5, Section 5.4.1, page 187).

As pointed out by several interviewees, the early stages of research are often hazy. Somebody has an idea that something may be important, but cannot necessarily explain that idea and is certainly not clear about any consequences of exploiting that idea. He/she may simply have a feeling that something about the *status quo* is not quite right, or that a current practice is inefficient or even wrong. Time is needed to investigate or experiment with the idea in order to come up with something more concrete that can then be shared and worked on with others. An individual approach is thus often the only way to proceed in the initial stages. However, this does not necessarily mean that a single disciplined approach is taken. As people experiment, and observe, and talk about their results with other people throughout the company and elsewhere, a multidisciplinary approach may emerge. This is particularly so in pharmaceutical research which, of necessity, involves the merging of ideas from biology, biochemistry, genetics, chemistry, pharmacology, and

many more disciplines, in order to understand the full implications of what is being carried out. In addition, although separate working areas are usually provided in the larger pharmaceutical companies, this does not mean that the disciplines are, in fact, totally separate from each other. Separate working areas are needed because certain activities require specific tools or environments that would be too expensive and unnecessary to provide on an 'across the board' basis. This does not mean that the producers of research knowledge are completely separated from the consumers of that knowledge. Indeed, most of these companies also provide dedicated cross-functional meeting areas.

Although new 'scientific' knowledge is one product of pharmaceutical research, the usual objective of that research is to provide a prototype – a candidate drug or therapy – for further development. It is hard to see how such an outcome can be achieved if there is no input at all from the development or business functions of the organization. In fact, as reported above (Section 6.2, page 212), these functions are increasingly involved early on in the research stages. Yet, knowledge production in research is clearly not truly Mode 2 in nature. Pharmaceutical researchers and the companies they work for are interested in promoting the fundamental science behind their activities, to the extent that companies mostly encourage their researchers to publish or otherwise share such results (Chapter 5, Section 5.4.1, page 183). In addition, understanding failure is also particularly important in research (Chapter 5, Section 5.3.3, page 175). The practice of pharmaceutical research, thus, echoes some of the collegial traditions associated with basic research conducted in an academic context, but the research agenda – what to tackle – is guided by commercial considerations. The findings presented in this thesis would suggest that perhaps the best description for knowledge production in pharmaceutical research is 'Transdisciplinary Mode 1, carried out with due regard to the commercial needs of the organization'.

Development

Pharmaceutical development is carried out more specifically for the distinct purpose of achieving a practical goal: the launch of a new drug or therapy. It is dependent upon there being a perceived business advantage (Chapter 5, Section 5.3.1, page 166). It *is* knowledge production carried out in the context of application (Chapter 3, Section 3.4.1, page 103).

Although interviewees generally referred to development teams as being multidisciplinary and multifunctional, according to the Mode 2 model, they are perhaps more appropriately described as *transdisciplinary*. While such teams are formed from a heterogeneous set of participants, their expertise evolves from the mix of disciplines and functions involved: it *transcends* the expertise of individual participants and cannot be reduced to the sum of its parts. Teams might embrace members from a diversity of fields, spanning, for example, the different areas of science, the business functions, organizations engaged in related activities, the regulatory authorities, various healthcare workers, patients and environmentalists, but the expertise that emerges from interacting together as a team is qualitatively different from the expertise possessed by any given participant. Clearly, teams are subject to constraints associated with the extent to which participants are able to commit to collective activity and to broader contextual factors in the form of regulatory requirements. However, they embody a considerable degree of autonomy: the work of the team *is* largely determined by the team itself and the results achieved. And, whilst project leaders might facilitate and coordinate the work of the team, they are simultaneously 'part of the team' and constrained by team expectations about what counts as acceptable.

Although the achievements of development teams may echo the contributions of leading participants, they also surpass the simple summation of individual contributions.

In line with Mode 2 working, development teams *are* temporary in that they exist for the duration of a project and team members *do* generally join and leave in accordance with the need for their particular skills. However, in contrast to Mode 2 working, team initiation and team changes are usually coordinated by a management body (Chapter 5, Section 5.3.2, page 170). Managers were said to have the breadth of knowledge to make decisions on project priorities and on relevant team membership. In addition, because of the length of a development project (typically 8-12 years) managers may proactively plan membership changes in order to overcome stagnation. Over a period of time, developers may also be promoted to other positions or move on to other companies. The proposition that Mode 2 teams form and dissolve in line with the evolving needs of the problem to be solved *without being planned or coordinated by a central body* (Chapter 3, Section 3.4.1, page 103) is one which has not therefore been attained in pharmaceutical development to-date.

Gibbons *et al's* view that firms will take on some of the characteristics of a spiders web would appear to be born out by the way in which companies in the pharmaceutical industry *do* collaborate and network with each other. Flows of information, knowledge, products, people and ideas *have* become important. But, at least in development, structure (in the form of the firm or the extended firm) also remains sacrosanct, since the flows of information, knowledge and ideas *are* tempered by commercial awareness. Thus, although collaborative working does involve the sharing of project specific knowledge, informal knowledge networking is observed to be of a general rather than a specific nature in

development. In development, what is not acceptable in an informal networking arrangement is legitimate in a structured and agreed arrangement. Formal collaborations thus define the rules of engagement within which people can freely work together. And, because of this, knowledge production in pharmaceutical development is perhaps better described as a 'Coordinated Mode 2' type activity.

In some ways, Mode 2 working might be thought to have similarities with the virtual learning systems of fifth generation R&D (Chapter 2, Section 2.2.5, page 29) since both approaches rely on the transient collaborative arrangements that exist between people within different organizations. However, fifth generation R&D implies the self-government of opportunistic alliances formed across distinct corporate entities (something that the companies studied herein would not appear to formally condone, alliance formation being a strategic rather than an *ad hoc* decision process). Mode 2 knowledge production on the other hand appears to advocate the self-governance of multiorganizational transdisciplinary teams working to solve a particular problem (something that companies do appear to condone implicitly if not explicitly).

The Implications of Mode 2 Working

Gibbons *et al* suggested several implications for Mode 2 working that organizations should pay heed to (Chapter 3, Section 3.4.1, page 105). The findings of this present study would suggest that most of these implications are evident in the UK pharmaceutical industry. For example, in line with Gibbons *et al's* first implication, most companies *do* recognize the permeability of knowledge across organizational boundaries – through formal

collaborations and via knowledge networking – and rather than seeking to build non-permeable knowledge walls they use the knowledge available to them to expand their knowledge bases. Isolation is highly undesirable in a rapidly changing scientific and technical environment. What is critical is not the movement of knowledge *per se*, but rather the ability to use and expand upon that knowledge.

In agreement with Gibbons *et al's* third implication, companies *do* recognize the need for collaborative rather than individual performance at the development stage, and they use matrix coordination to aid the reconfiguration of resources to meet the requirements of the problem in hand. However, one outcome of this way of team working is that much of the knowledge shared and created within one project team is not easily transferred to other project teams. End of project reviews can help, and some knowledge diffusion occurs as individuals move between teams, but in agreement with Gibbons *et al's* second implication, much of the team knowledge is lost to the organization. As noted in Chapter 5 (Section 5.4.2, page 191), one company is attempting to go some way towards stemming this loss by promoting cross-team participation. The assumption is that some of the existing knowledge will be applicable or may be adaptable for use in the new team context.

In line with Gibbons *et al's* fourth implication, all of the interviewees in this study *did* recognize that the scientific community *does* display many of the features of a global village. However, they rely on both their research and development staff to share only that knowledge that is appropriate.

As we saw in Chapter 5 (Section 5.4.1, Table 5.4.1, page 177; and Section 5.4.2, Table 5.4.3, page 189), R&D networks and alliances *are* used extensively in the

pharmaceutical industry, and universities and other research institutes *are* often part of these systems (Section 5.4.1, Table 5.4.2, page 186; and Section 5.4.2, Table 5.4.4, page 198). However, in contrast to Gibbons *et al's* fifth implication, many interviewees did not necessarily agree that the transient clusters of Mode 2 working would increasingly produce the specialist knowledge that will characterize the knowledge industries of the future. The Mode 1 approach that the various research organizations are traditionally known for is highly valued. Basic research is (still) expected to provide many of the scientific breakthroughs of the future, in much the same way that the biotechnology breakthroughs previously came about.[15]

No specific attempts were made in this present study to answer the three questions posed by Gibbons *et al* regarding stability, fungibility and insecurity (Chapter 3, Section 3.4.1, page 107). However, the findings herein might suggest the following.

First, pharmaceutical researchers do not necessarily look for stability, predictability or routine. In fact it is by observing the unexpected that new understanding and knowledge is created. What researchers do require is a supportive environment that accepts the failure that may result from instability, unpredictability and experimentation. In contrast, pharmaceutical developers are required to use a range of routine processes to adapt the work of others. The fact that some stability, predictability and routine is present may then perhaps atone for the intermittent and transitory unstable patterns of transdiciplinary working.

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[15] It should, perhaps, be pointed out here that, in a later report, Gibbons stated that it was not being argued that Mode 1 would eventually succumb to Mode 2, but that the terms of their co-existence would 'depend as much on the response of the institutes that are currently supporting Mode 1 as on the social diffusion of Mode 2.' (Gibbons, 2001, p.43)

Second, R&D is a continuous learning process. Change is expected. Moving scientists to new jobs which demand new skills and different knowledge profiles (that is, increasing fungibility) within the capabilities of these scientists is not recognized as a problem. However, time and support is needed for the acquisition of those new skills and knowledge profiles.

Third, the amount of insecurity that any one person can bear is subjective. Yet, the need for a supportive environment in R&D would perhaps suggest that insecurity should be kept at a minimum to increase creativity.

6.4 The Knowledge Creation Models and their relevance to Pharmaceutical R&D

6.4.1 Knowledge Creation after Nonaka and Takeuchi

In Chapter 3, there were essentially two major criticisms that were levelled at the knowledge creation model proposed by Nonaka and Takeuchi: first, it makes the assumption that four distinctly different forms of knowledge (explicit and tacit, of the individual and the group) can be converted into each other (Chapter 3, Section 3.2, page 79), something that would seem from their normal definitions to be impossibly difficult; and, second, it assumes, at least on the surface, a systematic flow of knowledge from the individual to the group to the organization and then beyond, which might be one way in which knowledge may flow, but is not necessarily the only way (Chapter 3, Section 3.4.2, page 110). The assumption of a knowledge conversion process is perhaps one reason why Nonaka and Takeuchi 'redefined' tacit knowledge to be that knowledge that is 'not *easily* visible and expressible, and which is thus *difficult* to communicate to or share with others' (Nonaka and Takeuchi, Chapter 3, Section 3.4.2, page 111, italics in original). And, it should perhaps be pointed out again that even Nonaka and Takeuchi do not necessarily see knowledge creation as the simple cyclic process they describe (Nonaka and Takeuchi, Chapter 3, Section 3.4.2, page 112). However, a third and more important criticism of Nonaka and Takeuchi's model stems from the simple observation that, because Polanyi shows us that all knowledge contains a tacit dimension, it seems unreasonable to accept the very existence of tacit knowledge and explicit knowledge as two distinct knowledge forms (Chapter 3, Section 3.4.4, page 119). In essence, Polanyi argued that

there was no such thing as explicit knowledge. Accordingly, Nonaka and Takeuchi's use of the term 'explicit knowledge', as if it could be attributed to Polanyi, involves an epistemological somersault.

One way to make Nonaka and Takeuchi's model 'work' might lie in redefining their terms. It is perhaps tempting to equate tacit knowledge with Polanyi's concept of *personal knowledge*, and explicit knowledge with information, since we have seen that, first, all knowledge is inherently personal (Chapter 3, Section 3.3, page 92), and, second, it is only information that can really be said to exist independently and thus be presented in explicit form (Chapter 3, Section 3.3, page 95). However, simply replacing tacit knowledge with personal knowledge and explicit knowledge with information in Nonaka and Takeuchi's model does not appear to reflect what these authors are trying to say. Yet, without a working definition that reflects the spirit of what Nonaka and Takeuchi might mean by tacit knowledge and explicit knowledge, it is difficult to relate their model to the findings presented in Chapter 5.

In the discussions that follow, tacit knowledge is treated as knowledge that is personal to the individual, or specific to the group, the organization and so on, but which cannot be commodified and transferred as if it were an object, whereas explicit knowledge is assumed to be a transferable commodity expressed in verbal or written language. These definitions rule out the possibility of any *conversion* between tacit knowledge and explicit knowledge, but they do not rule out the possibility that each form may be *used* to create new knowledge of either type, as so assumed by Cook and Brown (Chapter 3, Section 3.4.3, page 113). So, accepting the existence of explicit knowledge and tacit knowledge as defined, and accepting the use of one form of knowledge to produce new

knowledge, to what extent can Nonaka and Takeuchi's model now be used to describe knowledge creation in pharmaceutical R&D? The following paragraphs address this question, first for knowledge creation in research, and second for knowledge creation in development.[16] But, before proceeding, it should be emphasized that the discussions presented in this subsection are conducted at the *macro*-level, that is, at the level of the particular activity involved. Yet, knowledge is created at the *micro*-level, that is, at the level of the mind of the individual or individuals involved. Comments regarding this latter more elemental level are therefore made towards the end of each separate discussion on research and on development.

Research

Using the findings of Chapter 5, Figure 6.4.1 (next page) outlines the activities thought to be most important in pharmaceutical research. Although not drawn upon in this analysis, the numbered activities can be related to those suggested by Tang and presented in Chapter 2, Section 2.3, page 40.

Idea Generation: Pharmaceutical research begins with the generation of an idea that may either hint at the solution to an existing problem or suggest an improvement to the *status quo*. Although idea generation may be treated as a personal activity based upon the individual's existing explicit knowledge and tacit knowledge, within an industrial context it may be expected to be influenced explicitly or implicitly by organizational objectives

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[16] In the following pages, normal type font should be associated with the knowledge processes as described by Nonaka and Takeuchi, whereas italic type font should be associated with processes described by the 'use of knowledge to form new knowledge'

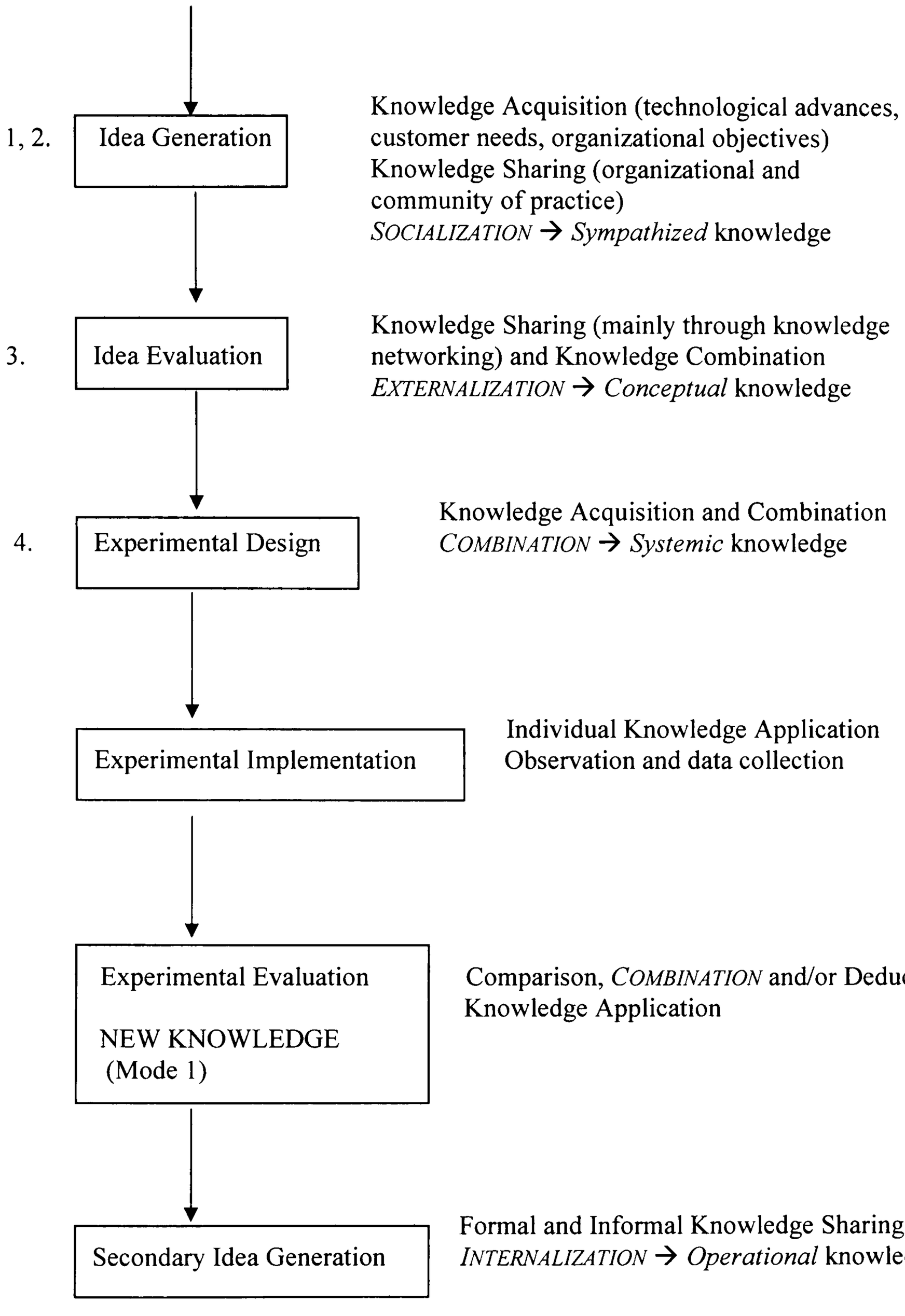

FIGURE 6.4.1: KNOWLEDGE CREATION IN PHARMACEUTICAL RESEARCH

(Chapter 5, Section 5.3.1, page 163). That is, the sharing of explicit knowledge, in the form of mission statements and strategic goals and the implications behind them, guides or defines the idea generation stage. Since research is largely a discipline-based activity, idea generation may also be influenced by the explicit knowledge and tacit knowledge held within the individual's relevant community of practice (for example, the knowledge held by the society of biologists, etc.). In Nonaka and Takeuchi's terminology, *socialization* within an organization or within a community of practice provides *sympathized* knowledge that enables the generation of relevant ideas. However, again, it should be emphasized that this should not be taken to imply the conversion of tacit knowledge to tacit knowledge, but rather the individual's use of explicit knowledge and tacit knowledge to yield new knowledge.

Idea Evaluation: Once an idea or problem has been identified there may be some 'vagueness' about how to proceed (Chapter 5, Section 5.3.2, page 167). Pharmaceutical research is perhaps unusual in that it regularly requires the combined knowledge and understanding of a number of scientific disciplines in order that the 'whole picture' can be seen and understood. What effect will the chemistry have on the biology? What effect will the method of infusion have on the rate of absorption of a drug and how will that affect biological reactions and activities? And so on. The initial approach taken in pharmaceutical research consequently requires a transdisciplinary evaluation of the idea to be used (Chapter 5, Section 5.4.1, page 186). In Nonaka and Takeuchi's terminology, *externalization* of the idea produces the *conceptual* knowledge needed to fully evaluate the usefulness of the idea. But, rather than the conversion of tacit knowledge to explicit knowledge, it is the use of the individual's existing tacit knowledge and explicit knowledge that enables an explicit representation to be made. Once this has been carried

out, and depending upon the predicted needs, the approach taken may be single-discipline based, multidiscipline based or transdisciplinary.

Experimental Design: When the overall approach has been decided, experimental design becomes important. What is actually required to validate the idea? To what extent can traditional tools and routines be used or combined in the process? What additional tools are needed? Can these tools be acquired or can they be built? Is a multidisciplinary approach or a transdisciplinary approach expected to be more effective? In contrast to what is commonly assumed to be a 'trial and error' process, considerable thought may be involved before any practical work commences. However, rather than a purely logical process, it would seem that researchers also use their intuition in deciding how to proceed. In fact, in some instances intuition may well be more important than logic. For example, two interviewees (Company-A-4, p.7 and Company-I, p.27) noted that some of their most successful research had its origins in activities that had run counter to conventional wisdom. So, rather than simply the *combination* of explicit knowledge to produce *systemic* knowledge (Nonaka and Takeuchi, Chapter 3, Section 3.4.2, page 108), it would seem that tacit knowledge may also be used at this stage of the process.

Experimental implementation: Experimental implementation is largely in the hands of the individual researchers (Chapter 5, Section 5.3.1, page 167). However, to the extent that everyone comes to the job with his/her own particular (scientific) baggage (Chapter 5, Section 5.4.1, page 179), 'community of practice' knowledge may also be expected to influence this stage of the process. Experimental implementation serves no purpose unless detailed and accurate observations of the results of any experiment are recorded for future reference. The observation and collection of data will be, in part, dependent upon the

tools, methods and procedures used. However, it will also depend upon the researcher being 'open' to the unexpected. Exactly how this 'openness' comes about is beyond the scope of this present study, but it seems reasonable to assume that it will be shaped by a fusion of the researcher's (tacit and explicit) experience and his/her capacity to construct coherent interpretations of here-and-now sense perceptions. Certainly what is unexpected to one person might go unnoticed by another, and, as a consequence, may not be recorded. Thus, we might say that the use of both explicit knowledge and tacit knowledge would also seem to be important at this stage.

Experimental Evaluation: The experimental data is then assessed for meaning and relevance. The determination of relevance may involve comparisons with previous results to either confirm or question existing findings. If the findings are confirmed, any new knowledge that results may then be combined with existing knowledge to produce additional knowledge. If the findings are questioned, additional experimental validation may be necessary to confirm the accuracy of the new and/or old data and their associated meanings. Alternatively, meaning may be deduced directly. Arguably, deduction may produce a meaning that is more subjective than is arrived at by the comparison method, since it relies only on the experimenter's interpretation of what has occurred, and this interpretation may be expected to be dependent upon the experimenter's previous tacit and explicit knowledge and skills set, particularly those due to his/her community of practice boundaries. Thus, what is meaningful to one person may not necessarily be so to another. Consequently, the knowledge created by one person may not necessarily be the same as that created by another.

Secondary Idea Generation: New knowledge might generate new ideas and generate new perceptions about what should be done next. The context of knowledge creation shapes these generative processes and, with regard to the present findings, formal project review meetings (Chapter 5, Section 5.4.1, page 186) and informal knowledge networking activities (Chapter 5, Section 5.4.1, page 182) were shown to be particularly important in shaping these ideas and perceptions. Additional ideas may then be incorporated into the design scheme, and the research process repeats until the desired result has been achieved – the idea concept has been proven or the problem has been solved – or the work is abandoned. In either instance, valuable new tacit and explicit *operational* knowledge will have been created and *internalized* for future use.

The way in which knowledge is created within pharmaceutical research thus illustrates the importance of activities that appear similar to Nonaka and Takeuchi's processes of socialization, externalization, combination, and internalization. However, pharmaceutical research also indicates that knowledge creation in research is more complicated than Nonaka and Takeuchi's model proposes (McAdam and McCreedy, Chapter 3, Section 3.4.2, page 110). First, it shows that the various ontological dimensions (individual, group, organization, etc.) may be involved within any one knowledge creation cycle. Second, it shows that both tacit knowledge and explicit knowledge are used *at the same time* during that cycle. Furthermore, at the *micro*-level of the individual, all sense making is a matter of observers – people – rendering their perceptions comprehensible. That is to say, meaning is constructed in the mind of persons: it is a continuous process of ordering and re-ordering sense perceptions and there is no logical reason why *internalization* should come after *combination* and before *socialization.* People make sense of the world – and *interiorize* their conclusions – on a continuous basis. As new

ways of acting and thinking become assimilated into the subconscious, they become a 'free resource' that can be re-used without incurring the time and effort to re-learn what is involved.

These findings do not, however, negate many of Nonaka and Takeuchi's other suggestions. For example, Nonaka and Takeuchi's five enabling conditions for new product development would appear to be mostly valid in pharmaceutical research. First, 'organizational intention' *does* guide pharmaceutical research, although the vision about what kind of knowledge should be developed and operationalized is perhaps more in the hands of the individual researcher than in the hands of research management. Second, 'individual autonomy' *is* clearly respected. Third, 'redundancy of information' *is* encouraged to promote understanding and learning between disciplines and within communities of practice across organizations. It is also deemed important for generating novel ideas. Fourth, research units *do* tend to have flat and flexible structures, and researchers *are* inter-linked with their organization's information network. They also have recourse to their own individual knowledge networks. So, in this sense, 'requisite variety' *is* probably present. However, whether the remaining enabling condition, 'fluctuation and creative chaos', needs application is perhaps questionable. UK pharmaceutical researchers would appear to be both reflective and focused in their approaches without the need for additional 'fluctuation and creative chaos.' Possibly, the fluctuation and creative chaos that have to be stimulated within a Japanese company-as-family workplace organization are, within UK pharmaceutical research, a natural consequence of the perturbations associated with British attitudes to personal ambition, liberal individualism and labour mobility.

Nonaka and Takeuchi's suggestion that the process of *socialization* would not appear to be as well developed in the West as it is in Japan would also appear to be confirmed by the present study, and there are perhaps three reasons why this may be so. First, research *is* often an individual activity. Second, when teams are formed they *are* usually dissolved with relative frequency. Third, it is possible that, within the UK, more formal management procedures – such as regular project review meetings – define prescribed activities that are carried out informally during the Japanese process of 'living and working together' (Harvey-Jones, 1993, p.178).

Development

Using the findings of Chapter 5, Figure 6.4.2 (next page) outlines the activities involved in pharmaceutical development. Again, the numbered activities can be related to those suggested by Tang (Chapter 2, Section 2.3, page 40).

Project Proposition: Given the high costs involved, pharmaceutical development begins in almost all instances with the submission of a written project proposal. This proposal may be based upon the results of internal or external research or upon suggestions for the further development of existing products, processes or procedures. In each case the idea to be used will have been proven in principle, or will be evident from the previous work undertaken. Proposals for development work are usually group-based, may arise from either technical or commercial considerations, and must take both technical and commercial factors into account. There is typically a defined route to commercialization and proposals will normally include an initial evaluation against set criteria such as cost

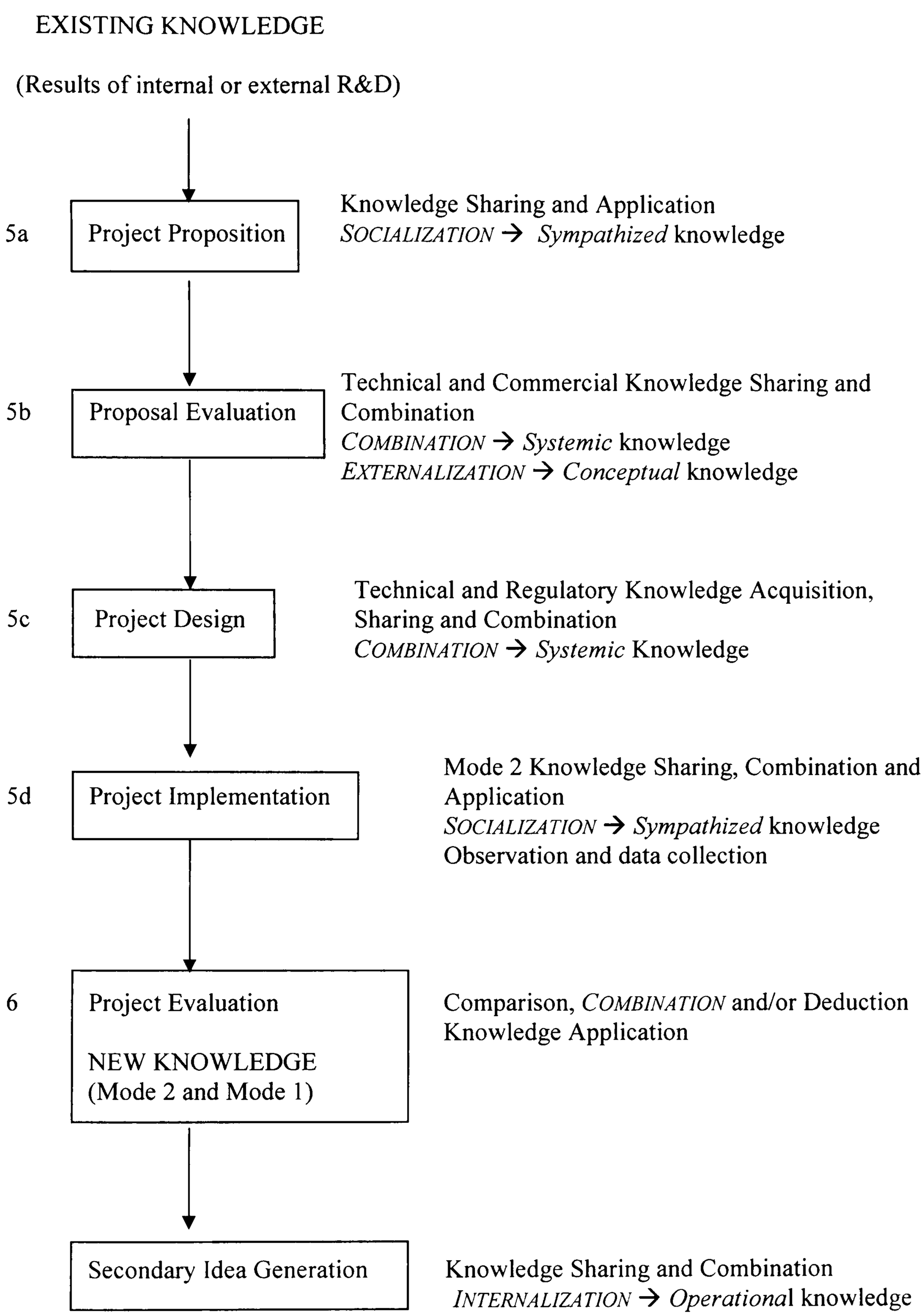

FIGURE 6.4.2: KNOWLEDGE CREATION IN PHARMACEUTICAL DEVELOPMENT

and time estimates (Chapter 5, Section 5.3.2, page 169). However, such an evaluation is far from exact, and whether or not a proposal is actually put forward for consideration is perhaps based as much upon intuition as upon fact. Thus, the *sympathized* knowledge held within the organization may be expected to take both tacit and explicit forms and may be expected to influence project proposition in much the same way that it influences the generation of ideas in research.

Proposal Evaluation: Development proposals are then critically assessed for their commercial viability and commercial and technical advantage. Assessments are usually carried out by a team consisting of the relevant research, development and commercial managers working in an essentially transdisciplinary manner. In some companies the assessment team may also include the 'scientific advisory team'. Assessments are therefore based upon the team's combined knowledge. The assessments undertaken at this stage are arguably more objective than the initial evaluations made by the proposer(s), but they are, of necessity, still based upon a significant amount of guesswork. The tools required to do the job may be largely known, the costs of the expected tests and clinical trials may be known, the staff to be allocated to the process may be known, but the number (and therefore the costs) of the modifications needed to complete the work is largely estimated. Whilst this explicit knowledge is vitally important, the assessment may also include an interview with the proposer(s), the purpose being to obtain a better understanding of the thinking and reasoning behind the proposition. What, *was* the reason for the submission of the proposal? What *are* the outstanding points to be considered and what really *are* the expected outcomes? By trying to *externalize* some of the tacit reasoning behind the proposal, it is perhaps hoped that a better decision can be made on whether or not the proposal should be advanced.

Project Design: Accepted proposals are usually allocated a project manager and the detailed project design and implementation stages commence (Chapter 5, Section 5.3.2, page 169). Project design in development is transdisciplinary in that the various disciplines design the work together with one end in mind: regulatory acceptance of a new and valuable product into the health care market, a product that has financial value to the company, and which is also valuable to consumer health (Chapter 5, Section 5.3.2, page 168). However, many of the components of the overall design will be based upon routine scientific techniques and standard processes. For example, clinical trials and tests for safety and efficacy will require adherence to predetermined procedures. It is not impossible, but it is not easy, to change regulatory requirements. It is certainly expensive. Project design is also transfunctional: financial, manufacturing and marketing possibilities and needs are designed in from the beginning, as well as being considered throughout the implementation process. Regulatory and ethical requirements are designed in likewise. In fact, moral issues concerning drug and therapy testing, availability and supply are increasingly affecting what work is undertaken and how it is carried out. Project design may also be transorganizational. As noted above, although collaborations are invariably agreed by formal contract, it is generally accepted that the collaborating participants work (and therefore design) together as one team (Chapter 5, Section 5.4.2, page 201). Project design in development thus involves the sharing and combination of knowledge across a number of ontological dimensions (community of practice, organizational and inter-organizational) at the same time, rather than sequentially as suggested by Nonaka and Takeuchi's model. In addition, although much of the knowledge involved is explicit, intuition (tacit knowledge) may also play a part in the design process in much the same way as it does during 'experimental design' in research (page 230 above).

Project Implementation: Project implementation is a team process, involving members from the various disciplines, functions, and organizations working together to get the job done. Although the different types of work undertaken (product development, formulation, manufacture, clinical testing, stability studies, etc.) may be carried out at different locations, a *coordinated* Mode 2 type approach is used (Section 6.3, page 221). Project implementation (like experimental implementation in research) is also dependent upon the detailed and accurate recording of experimental observations. And, again, different observers may 'see' the same 'reality' in different ways, so that what is actually observed may depend to some extent upon the observer's existing tacit knowledge and explicit knowledge in much the same way as for experimental implementation in research (page 230 above). Working in an essentially Mode 2 manner thus involves to some extent the sharing, combination, and application or use of knowledge from across both the epistemological and ontological dimensions.

Project Evaluation: A Mode 2 type implementation might be assumed to ensure a Mode 2 type evaluation of the experimental findings. Certainly, the recorded data will be interpreted and much meaning will arise from the context of application. However, it may perhaps also be expected that new disciplinary meaning will also arise from the actual scientific experiments carried out. Hence, Mode 1 disciplinary knowledge may be produced within the minds of the individual team members, whilst context-specific Mode 2 knowledge may result from the transdisciplinary, transfunctional, transorganizational team activities undertaken together. In either case, meaning may, again, be expected to be based upon the individual's or the group's existing tacit and explicit knowledge and skills set.

Secondary Idea Generation: To the extent that new meaning may be assumed to generate additional ideas to be used or problems to be solved, the secondary ideas generated may also be expected to take both 'Mode 1' and 'Mode 2' forms. The *operational* tacit and explicit knowledge generated and *internalized* by the team members during pharmaceutical development may therefore be expected to be both discipline-based and project-based. Whilst the new *internalized* project-based knowledge will take precedence throughout the course of the existing development, its relevance to future activities is perhaps questionable: its usefulness will depend upon the ability of its 'holders' to understand its meaning within the new context of application. The new *internalized* discipline-based knowledge, on the other hand, will form part of each individual's enhanced 'tool kit' and may well prove useful in future contexts.

The way in which knowledge is created within pharmaceutical development thus also illustrates the importance of activities that appear similar to Nonaka and Takeuchi's processes of socialization, externalization, combination, and internalization. However, again, knowledge creation is more complicated than Nonaka and Takeuchi's model might suggest. Again, it would appear that the various ontological dimensions (individual, group, organization, etc.) may be involved within any one knowledge creation cycle. And, again, both tacit knowledge and explicit knowledge would appear to be used at the same time. Furthermore, at the *micro*-level of the individual (within the group, organization, and so on), meaning is, again, a continuous process of ordering and re-ordering sense perceptions and interiorizing the personal conclusions so formed (see page 232, above). Moreover, where close community relationships among team members enable these members to make sense of the world in an aligned way, it is possible to communicate a great deal with a minimum of information: shared experience helps participants to 'see' the

same 'reality' in an aligned way. The group can re-use its shared experience as a tool or 'free resource' for 'getting things done'. In Nonaka and Takeuchi's vocabulary, the effect is similar to *socialization* but the shared experience that enables insiders to see the same reality in a similar way is reflexively automatic. It is not possible to 'unlearn' or 'suspend' the tacit knowing that underpins sense making. For example, by talking to our best friend as if he or she were a stranger, we do not necessarily revise our estimates about friendship. As a corollary, creating knowledge about friendship need not necessarily involve *externalization*.

Some of Nonaka and Takeuchi's five enabling conditions for new product development would also appear to be valid in pharmaceutical development. First, 'organizational intention' *does* guide and even determines pharmaceutical development. Second, development units *do* tend to have flat and fairly flexible structures, and developers *are* inter-linked with their organization's information network. They also have recourse to their own individual knowledge networks. So, 'redundancy of information' *is* accepted (if not necessarily encouraged) and 'requisite variety' *is* probably also present. However, whether 'individual autonomy' within a team environment *is* respected is unclear, and whilst some 'fluctuation' is present in the sense that teams form, disband, and reform, 'creative chaos' would not appear to be the intention.

Again, Nonaka and Takeuchi's suggestion that the process of *socialization* is not as well developed in the West as it is in Japan, is perhaps also confirmed in pharmaceutical development. The type of close community relationships among colleagues who spend their career working, learning and innovating together, which are taken for granted inside Japanese organizations, are rare amid British expectations about liberal individualism and

labour mobility. Even though development is a team activity, UK teams are still formed and dissolved with relative frequency. The possibility of working together, on a long-term basis, in the manner of a Japanese team is difficult to imagine without the Japanese institutions that lend legitimacy to this style of working.

Despite the confirmation of much of what Nonaka and Takeuchi observe, the findings of this present study would suggest that, even when modified in the way described within this subsection, the knowledge creation model that they propose does not appear to adequately reflect what happens in either a research or development environment. The next subsection therefore moves on to investigate the modifications made by Cook and Brown.

6.4.2 Knowledge Creation after Cook and Brown

Cook and Brown retain the assumption that explicit knowledge and tacit knowledge, of the individual and the group, exist as four distinct forms. Their model might therefore be rejected for this reason alone. But, let us, for the time being, adopt the stance taken in Section 6.4.1 above, and assume that tacit knowledge is personal to the individual, or specific to the group, the organization and so on, whereas explicit knowledge is assumed to be a transferable commodity expressed in verbal or written language (Section 6.4.1, page 226). Cook and Brown's proposition that one form of knowledge can be used as a useful tool in the generation of the other then neatly overcomes the problems associated with the existence of a conversion process between these two different forms of knowledge. It also accommodates the observations of this present study that the differing

forms of knowledge can be used at the same time during the activities associated with research and development. That is, it probably *is* reasonable to say that the production of new knowledge *does* lie in the 'use of knowledge as a tool of productive inquiry as part of our dynamic interaction with the things of the social and physical world' (Cook and Brown, 1999, p.397). Cook and Brown's framework thus does appear to offer a more appropriate representation of the organizational knowledge creation processes in pharmaceutical research and development. Yet, we might question whether the 'productive inquiries' involved are the result of a 'generative dance' between knowledge and knowing, since might they not, alternatively, be the result of an act of 'tacit knowing' (Polanyi, Chapter 3, Section 3.4.4)? For the present, this section will adopt Cook and Brown's view in order to investigate further how their model might be used to explain knowledge creation in research and development.

Research

Applying Cook and Brown's model to the research activities outlined in Section 6.4.1 above (pages 227-232), suggests the following framework for knowledge creation in pharmaceutical research (Figure 6.4.3, next page).

Idea Generation (page 227): The individualistic and intuitive nature of 'idea generation' in research would suggest that the predominant forms of knowledge involved in this activity are individual explicit knowledge and tacit knowledge. However, the fact that much of the individual's personal knowledge will be influenced by his/her community of practice knowledge, combined with the fact that ultimately ideas will need to fit with the

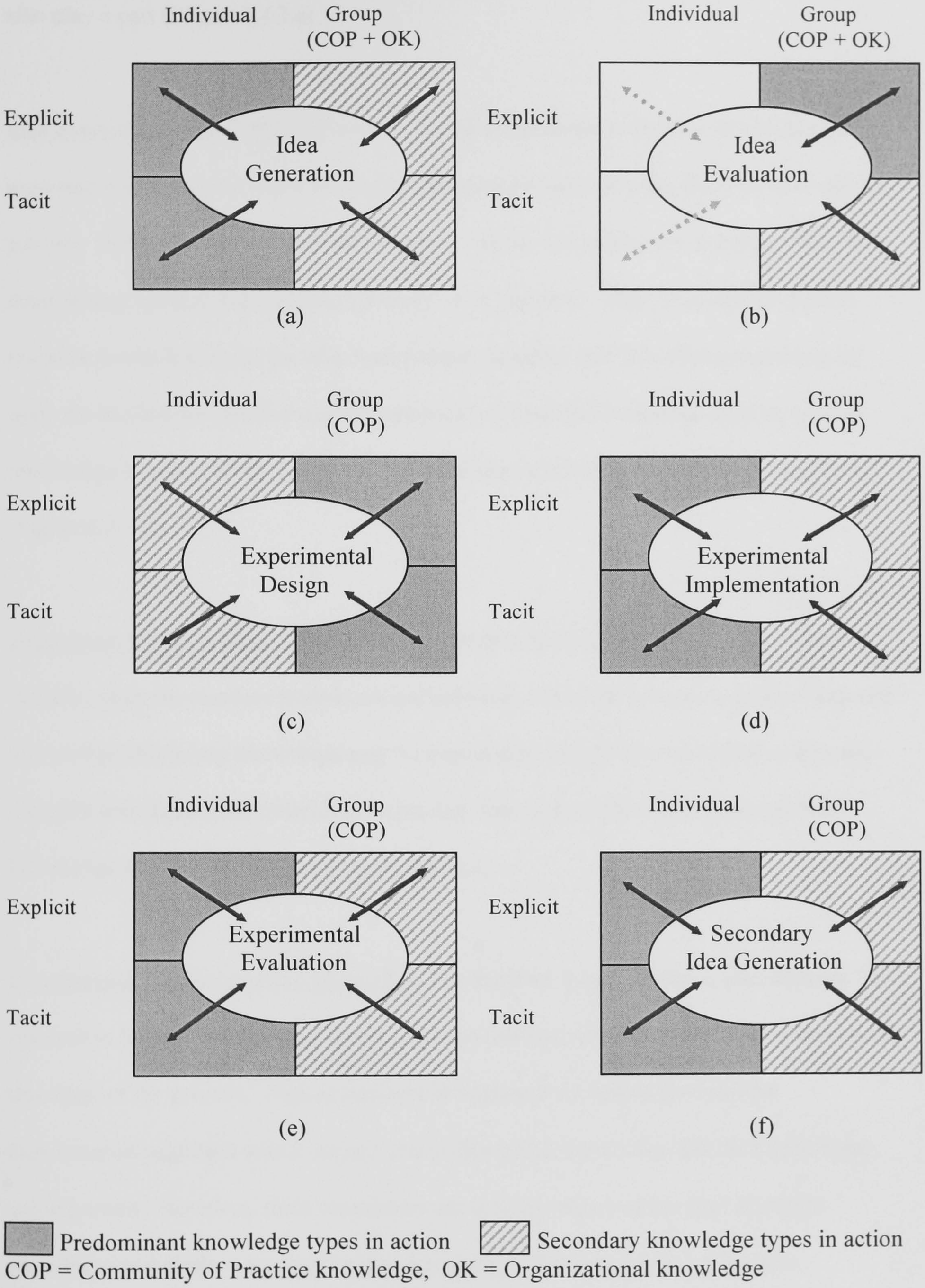

FIGURE 6.4.3: KNOWLEDGE AND KNOWING IN PHARMACEUTICAL RESEARCH

organization's objectives suggests that group explicit knowledge and tacit knowledge may also play a part (Figure 6.4.3.a).

Idea Evaluation (page 229): The need for a transdisciplinary evaluation of the idea that is proposed would suggest that group knowledge predominates during the 'idea evaluation' activity. Whilst business knowledge is input, it is not necessarily the deciding factor in determining whether the evaluation is positive or negative. What is more important in research is whether or not the idea is technically feasible, and this will be based largely upon the explicit and implicit use of community of practice knowledge; that is, explicit knowledge is used overtly, but tacit knowledge may also influence evaluation decisions (Figure 6.4.3.b).

Experimental Design (page 230): Whilst 'experimental design' may be based, at least initially, upon the standard techniques and practices of the relevant community of practice knowledge, this group knowledge may be expected to be significantly influenced by the thoughts and ideas of the individual researcher, that is, by his/her individual explicit knowledge and tacit knowledge (Figure 6.4.3.c).

Experimental Implementation (page 230): The fact that 'experimental implementation' in research is largely an individual activity, means that individual knowledge predominates at this stage of the process. And, as outlined in Section 6.4.1 above, the need for experimental cognition would suggest that both explicit knowledge and tacit knowledge are important. However, since researchers are mainly employed for their scientific knowledge and skills, once again it may be expected that community of practice knowledge will influence this activity (Figure 6.4.3.d).

Experimental Evaluation (page 231): Similarly, 'experimental evaluation' is predominantly an individual activity, but, one which, once again, may be expected to be highly influenced by the individual's community of practice knowledge. And, since the meaning associated with the evaluation of data results from an interpretive act, we might again expect that both explicit knowledge and tacit knowledge are involved (Figure 6.4.3.e).

Secondary Idea Generation (page 232): Since the knowledge created in research is shared mainly within the scientific community, 'secondary idea generation' might be expected to involve the use of individual explicit knowledge and tacit knowledge, influenced by 'community of practice' explicit knowledge and tacit knowledge, in much the same way in which the original 'idea generation' made use of those same knowledge forms (Figure 6.4.3.f).

Although Figure 6.4.3 suggests that knowledge creation in research is mainly an individual and discipline-based activity, to propose that it is simply Mode 1 knowledge production is clearly a simplification too far.

Development

Applying Cook and Brown's model to the development activities outlined in Section 6.4.1 above (pages 234-239), suggests the following framework for knowledge creation in pharmaceutical development (Figure 6.4.4, next page).

Project Proposition (page 234): The need for a formal written proposal prepared with due regard to the commercial and technical implications of the work to be undertaken, implies

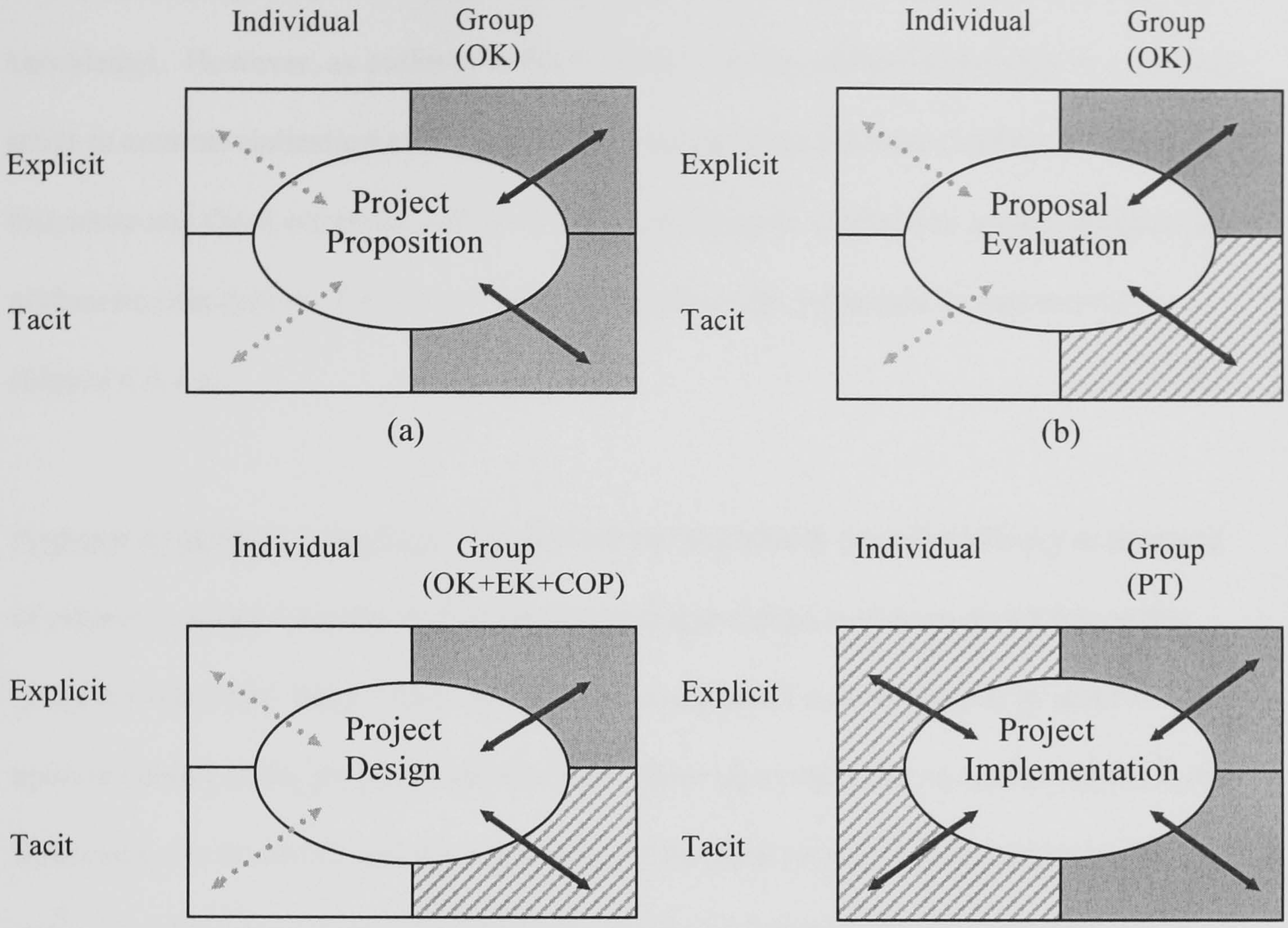

FIGURE 6.4.4: KNOWLEDGE AND KNOWING IN PHARMACEUTICAL DEVELOPMENT

that 'project proposition' is mainly a group (organizational) activity based upon explicit knowledge. However, as outlined in Section 6.4.1 above, whilst there might be a defined route to commercialization and whilst initial cost and time estimates will have been given, this route and these estimates will be based as much upon intuition as upon theoretical and arithmetic calculation. Tacit knowledge is therefore also important in this activity (Figure 6.4.4.a).

Proposal Evaluation (page 236): The critical and essentially transdisciplinary assessment of project proposals implies that organizational knowledge is also involved during the 'project evaluation' stage. And, whilst these assessments are undertaken in order to check upon the detail of the proposal and determine more accurately the resources required, the financial costs involved, and the importance of the final product to the company, the evaluation does nevertheless still involve a degree of 'expert opinion'. Whilst explicit knowledge predominates, it might be expected that actual decisions will be influenced by group tacit knowledge (Figure 6.4.4.b).

Project Design (page 237): The 'project design' stage in development is essentially a transdisciplinary activity, based upon the use of standard techniques and practices, and thus upon group (community of practice, organizational, and possibly external) explicit knowledge. However, the incorporation and appropriateness of these techniques will be, in part, based upon the judgement of those involved, and thus upon their group tacit knowledge (Figure 6.4.4.c).

Project Implementation (page 238): The team-based approach to 'project implementation' suggests the use of group (project team) knowledge during this stage of the development

process. Whilst the procedures outlined and the experimental work conducted might be assumed to involve predominantly explicit knowledge and data collection, the tacit understandings behind these procedures and the interpretations made as to which data should be collected imply the use of tacit knowledge. Also, since particular aspects of the work undertaken may involve the work of the lone developer (not everyone in the team will perform a particular clinical procedure, for example), it is conceivable that this group knowledge may be influenced by the explicit knowledge and tacit knowledge of the individuals employed (Figure 6.4.4.d).

Project Evaluation (page 238): Whilst Mode 2 type knowledge is the desired outcome of development, as outlined in Section 6.4.1 (page 238), Mode 1 type knowledge may also result from the experimental work carried out by the individual developers. 'Project evaluation' may then be expected to yield new meanings that may be both (A) individual and (B) group (project team) based. And, these new meanings may, again, be expected to be dependent upon both the explicit knowledge and tacit knowledge of the individual or the group (project team) (Figure 6.4.4.e).

Secondary Idea Generation (page 239): Similarly, the action of 'secondary idea generation' will predominantly be based upon group (project team) explicit knowledge and tacit knowledge, although individual ideas may be generated and used elsewhere (Figure 6.4.4.f).

Figure 6.4.4 suggests that although knowledge creation in development *is* mainly a group-based activity carried out in the context of application, to propose that it is simply Mode 2 knowledge production is also a simplification too far.

Coupling Cook and Brown's framework with the basic activities involved in pharmaceutical research and pharmaceutical development has graphically shown us some of the intricacies of and the differences between the knowledge creation processes in these two environments. In particular, it has highlighted the fact that knowledge creation in each of these activities is more complicated than the links to respectively, the Mode 1 and Mode 2 approaches suggested by Gibbons and his co-workers: organizational knowledge is integral to research activities, and disciplinary knowledge may result from the team working employed in development. It has also highlighted the fact that both explicit knowledge and tacit knowledge (as defined within this section) appear to be employed at the same time in all of the activities assumed important for knowledge creation in research and development. So, again, we might question whether such a split is valid. An additional concern, and one which is perhaps more a question of terminology than actual intention, is that Cook and Brown's assumption of a 'generative dance' between knowledge and knowing suggests to the present author a degree of randomness that is not necessarily present in the way in which we each approach the things that we do. For example, when we attempt to generate an idea, at least within a corporate setting, is there not some purpose to our thoughts? When we attempt to solve a problem do we really employ a random 'dance' between two entities called knowledge and knowing? Even if we cannot always say what it is that we are trying to find or trying to do, do we not, instead, think our thoughts and pursue our actions in the light of what we are trying to find or trying to do, or upon which our innermost thoughts and actions are focusing? So, can perhaps the application of Polanyi's work add more to the discussion than has so far been possible? The next section investigates this possibility.

6.4.3 Knowledge Creation after Michael Polanyi

Polanyi has shown us that by exploratory indwelling in the particulars of the 'clues' available to us, we arrive at a meaning of these particulars in the context within which we are operating (Polanyi, Chapter 3, Section 3.4.4, page 117). Furthermore, Polanyi has suggested that, in participating in this act of tacit knowing we are guided by sensing the presence of a hidden reality toward which these clues are pointing (Polanyi, Chapter 3, Section 3.4.4, page 120). So, adopting Polanyi's perspective, we view each of the activities within the research and development processes as acts of tacit knowing. In so doing, we do not, of necessity, assume the existence of explicit knowledge and tacit knowledge as distinct forms. Neither do we assume the knowledge conversion process proposed by Nonaka and Takeuchi, nor the generative dance between knowledge and knowing suggested by Cook and Brown. Rather, the creation of new knowledge occurs as we focus on the object of the act of tacit knowing, whilst dwelling in the particulars of that act of tacit knowing. Knowledge creation in pharmaceutical research and development might then be described as follows.

Research

Table 6.4.1 (next page) lists the acts of tacit knowing assumed in pharmaceutical research.

Idea Generation: Ideas for new products or for solutions to existing problems may arise from anywhere: from the science or technology involved; from business opportunities or threats; from the emergence of new strains of bacteria, etc. Nevertheless, in order for the idea to be worthy of further investigation, it increasingly has to be seen to have value to the

TABLE 6.4.1: THE ACTS OF TACIT KNOWING IN RESEARCH

Act of Tacit Knowing	**Focus (distal component)**	**Particulars (proximal component)**
Idea Generation	Unmet medical needs of society	Organizational objectives, skills, interests and available knowledge
Idea Evaluation	The chosen idea or problem solution	Potential and technicalities of the idea
Experimental Design	Desired project outcome	Science involved and skills available
Experimental Implementation	Practical execution of the experimental design	Technology involved
Experimental Evaluation	Experimental data	Science and technology involved

organization (Chapter 5, Section 5.3.1, page 163). In the pharmaceutical industry this will normally mean that the idea will be related to meeting the unmet medical needs of a particular 'society' of interest. At the same time, the insight behind the idea will be influenced by the individual researcher's skills, interests, aspirations, and any limiting issues such as lack of confidence in a particular area of expertise, etc. So, we might say that by focusing on the unmet medical needs of the society of interest, whilst dwelling in the objectives, skills, interests and knowledge of the organization, the individual researcher may be said to participate in an act of tacit knowing which may suggest a way forward: an idea for a new product is born, or a suggestion as to how a particular problem may be solved is arrived at.

Idea Evaluation: Initially ideas are 'fuzzy' and difficult to describe. There may be no clear way to proceed and there may be some doubt as to whether any attempt should actually be made to proceed. We have seen that, in the early stages of research, the evaluation of ideas

lies largely in the hands of the individual researcher, and will therefore, to some extent, be dependent upon that researcher's existing skills set. However, by communicating with others within and without the organization, the researcher is able to canvas opinion as to whether or not the idea is valid, what solutions may already exist, and what problems may in due course arise. By evaluating these factors in the light of the commercial potential to the organization, the individual researcher will then decide whether or not the idea is worthy of further examination (Section 6.4.1, page 227). We might say that by focusing on the idea, whilst dwelling in the potential and the technicalities associated with that idea, the researcher participates in an act of tacit knowing that provides the personal justification needed for the idea to be worked upon.

Experimental Design: Once justified, experimental design then becomes important. What is the best route to success? Can we use standard techniques to reach the desired outcome, or do we need new ways of doing things? What are the criteria necessary for verifying success? Who needs to be involved? As we have seen above (Section 6.4.1, page 230), whilst the design will be influenced by the existing knowledge and skills available to the organization, intuition is also thought to play a part in the process. So, we might perhaps say that by focusing on the desired outcome of the experiment, whilst dwelling in the particulars of the science involved and the skills available, the researcher participates in an act of tacit knowing which suggests the initial approach to be taken.

Experimental Implementation: Whether or not experimental procedures are designed jointly with others, experimental implementation is largely an individual activity, although one which is nevertheless influenced by the available tools and the researcher's practical competence. And, whilst the practical work may be explicitly described, the data collected

may be dependent not only upon the researcher's observational skills, but also upon his/her interpretation of what should or should not be recorded. Despite the expectations of objectivity, we cannot be sure that experimental implementation is necessarily free from personal interpretation (Section 6.4.1, page 231). Hence, we might suggest that by focusing on the execution of the experiment, whilst dwelling in the practicalities of the technology involved, the researcher participates in an act of tacit knowing which results in the production of data, which may or may not be free from subjective influence.

Experimental Evaluation: The result of an experiment may or may not confirm the viability of the chosen route to project completion, but the collection of data will, nevertheless, offer the researcher clues as to why success was achieved or failure occurred. By interpreting these clues and understanding the logic behind these clues, the researcher can start to increase his/her understanding of the science and technology involved, and thus improve upon the previous work undertaken. We might say that by focusing on the clues that the data provide, whilst dwelling in the science and technology involved, the researcher increases his/her understanding and brings new meaning to that data. And, by sharing this understanding and meaning with others, the researcher adds to the body of scientific and technical knowledge, which, in turn, may suggest new ideas or hint at new problems to be solved.

Development

In one sense, knowledge creation in development is less complicated than knowledge creation in research because the 'clues' to progress are more clearly defined: the research product or technique to be developed needs to meet the standard regulatory requirements for drug approval. In another sense, knowledge creation in development is more complicated than knowledge creation in research because it depends upon a group of individuals working together towards one goal that is understood and shared by all. However, since distinct activities are carried out by different individuals, we might ask the question: how does individual knowledge creation interact with or affect team knowledge creation and vice versa? The results in Chapter 5 have shown us that development teams within the organizations studied consist of people who bring their own particular skills to the team process. It would therefore seem plausible that individual knowledge creation adopts a functional or disciplinary perspective, whilst team knowledge creation adopts a strategic perspective. However, in order that an effective strategy be developed, it is important that the individual team members understand each other and the implications of the knowledge they bring to the process. Polanyi has shown us how, by exploratory indwelling in the thoughts and actions of others, we learn from each other (Chapter 3, Section 3.4.4, page 117). This is the assumption that has been made in the following paragraphs as regards the creation of team knowledge in development.

Table 6.4.2 (next page) lists the acts of tacit knowing assumed in pharmaceutical development.

TABLE 6.4.2: THE ACTS OF TACIT KNOWING IN DEVELOPMENT

Act of Tacit Knowing	**Focus (distal component)**	**Particulars (proximal component)**
Project Proposition	Desired project outcome	Technical and commercial issues of relevance
Proposal Evaluation	Projected outcome	Commercial and technical details of the project proposition
Project Design	Proposed route to development	Technicalities involved
Project Implementation	Practical execution of the development plan	Technicalities involved
Project Evaluation	Experimental data	Functional and disciplinary knowledge involved

Project Proposition: Project proposals in development are based upon existing assumptions (Section 6.4.1, page 234). Although these assumptions will have some justification in fact – a prototype product or process will have already been synthesized – these assumptions may yet prove false in the light of the additional knowledge obtained during detailed clinical trials, production scale-up, etc. Nevertheless, in proposing the project, the view will have been taken that the project is worthwhile, and this worthiness will have been based upon the knowledge and experiences held within both the commercial and technical departments. We might say that by focusing on the expected outcome, whilst dwelling in the anticipated technical and commercial issues involved, the proposers participate jointly in an act of tacit knowing that results in a written statement of the envisaged route to commercialization.

Proposal Evaluation: The evaluation of the project proposal also requires input from the commercial and technical departments. It involves an investigation into the project's importance in relation to the organization`s existing priorities, a more detailed evaluation

of resource and time estimates, and, where possible, the clarification of uncertainties (Section 6.4.1, page 236). Yet, whilst an overall budget for the project may be estimated with some certainty, the final outcome of the project cannot be guaranteed. We might therefore say that by focusing on the projected outcome, whilst dwelling in the commercial and technical details of the project proposition, the assessors jointly participate in an act of tacit knowing that results in an acceptance or rejection of the submitted proposal.

Project Design: Whilst many of the components of the project design will be based upon the standard procedures and practices of the separate functional departments, the overall design is a team-based activity (Section 6.4.1, page 237) with the various members from the separate functions working together to produce a detailed plan of the work that needs to be done, when that work needs to be done, and within what cost that work should be done. Thus, we might say that by focusing on the proposed route to development, whilst dwelling in the technicalities involved, the team jointly participates in an act of tacit knowing that results in a detailed plan of the way ahead.

Project implementation: Project implementation is essentially a transdisciplinary process with the various team members – pharmacists, toxicologists, chemical engineers, marketers, regulators, etc. – working together and adapting practices and procedures in complex and changing ways (Section 6.4.1, page 238). For example, what will be the effect on product yield of using a different grade of raw material? Will the use of a cheaper raw material adequately compensate for any increased purification costs? And so on. Yet, much of the work is actually carried out on an individual basis. For example, toxicologists will check product toxicology in the standard way, chemical engineers will apply their skills to the scale-up of production, buyers will use their negotiating skills to

source raw material, and so on. Yet, whilst the data collected during project implementation will depend upon the use of the relevant standard tools and techniques, the results obtained will not necessarily be free from personal interpretation. So, we might suggest that by focusing on the execution of the development plan, whilst dwelling in the technicalities involved, team members separately and jointly participate in acts of tacit knowing that produce the data upon which further progress may be determined.

Project Evaluation: Within the organizations participating in this present study it is clear that both disciplinary and transdisciplinary working occurs in development (Chapter 5, Section 5.3.2, page 169). Whilst disciplinary working has the potential to add to the knowledge of that discipline in much the same way as occurs during experimental evaluation in research (page 253, above), the main purpose of disciplinary working in development is to provide the data needed for a transdisciplinary assessment of what should be done next. We might therefore say, that by focusing on the clues that the data provide, whilst dwelling in the functional and disciplinary knowledge involved, developers jointly participate in acts of tacit knowing that provide the meaning behind that data in the context of the application and hence bring new ideas and suggestions for the way forward.

Viewing knowledge creation from Polanyi's perspective thus provides alternative descriptions of the knowledge creation processes in research and development, descriptions which appear to confirm Polanyi's original statement that tacit knowing can account for a valid knowledge of a problem [idea] and for the scientist's capacity to pursue it (Polanyi, Chapter 3, Section 3.4.4, page 120).

6.5 Knowledge Creation in Research and Development:

Why things are as they are

Research

Many of the seeds of knowledge creation in pharmaceutical research emerge from ideas that are associated with established scientific disciplines. On this account, they might owe more to the relatively stable tradition of scientific research than the vicissitudes of management fashion. To be sure, direction may be given to the research process – for example, the company's overall strategies and goals can be made clear through corporate mission statements, company briefings, project review meetings, and internal networking activities – but this direction is in the form of guidance rather than strictly laid down rules of engagement. It has to be so: research is speculative.

Research is also viewed very much an individual activity, and individual researchers are given a great deal of freedom and flexibility in the work that they undertake and the way in which they undertake it. Research projects are monitored and evaluated, but the monitors and evaluators are, at least in the early days, the researchers themselves. Researchers are the experts within their disciplines who are best informed to decide whether or not a particular technical path should be progressed (Jewkes *et al,* 1958, p.136).

The application of knowledge is important in research to the extent that researchers use the knowledge and skills available to them in the activities that they undertake. Since much of the knowledge important to research lies in the scientific community at large, access to the

scientific literature and to community of practice activities is crucial for success in research. Such access enables researchers to keep abreast of the latest developments in their fields of experience and expertise, and avoids the time and resources that may otherwise be wasted on duplication. Networking activities fit with the flexibility needed by researchers to access the knowledge that they require when they know that they require it, and also to access knowledge that they may not know that they require until they have acquired it. These facts were recognized by all of the interviewees in this study, and rather than attempting to control the access to such knowledge sources, they allow and in most cases encourage their researchers to use these sources accordingly. In general, these companies also encourage their staff to add to the knowledge within these sources by presenting and otherwise publishing their work, albeit with due regard to intellectual property considerations. Sharing scientific and technical knowledge within their peer groups also enables researchers to gain support for work that may be highly speculative and risky. It can lead to suggestions concerning problems that may be encountered, and ways in which these anticipated problems may possibly be overcome. And, 'bouncing' ideas off other people can suggest additional ideas for further research.

Knowledge networking is dependent upon a degree of understanding between the individuals involved. Words may be exchanged, but unless the meaning behind those words is understood it is unlikely that any knowledge will be exchanged or shared. Knowledge networking is also said to be dependent upon a degree of reciprocity. However, many scientists will freely share their basic knowledge in the hope of furthering the general understanding of the science and technology involved. What is hoped for is constructive and knowledgeable feedback rather than reciprocity (I will give you this knowledge if you give me some in return) *per se*.

Several interviewees noted that their companies had acquired specific scientific and technical knowledge through company acquisition or merger. This was particularly so when companies moved into new fields of activity. Companies may also hire-in specific expertise or employ people with particular experience for the same purpose (Chapter 5, Section 5.4.1, page 181). At the strategic level, the knowledge available to the company can in this way be directed and controlled. The direction or control of this knowledge at the practical level will however remain in the hands of the individual researchers.

The paragraphs above suggest that although some direction can be applied to knowledge creation within research as noted by Jewkes and co-workers, very little control can be exerted over this process (Jewkes *et al,* 1958, p.137). Indeed, it would appear that it is the basic needs of research that largely determine how corporate research is managed, what types of knowledge are needed for research, and ultimately how knowledge is created in research. Figure 6.5.1 (next page) shows this diagrammatically. The figure outlines the practice of pharmaceutical research from the view of (a) the basic needs of research, (b) the management of research, (c) the knowledge needs of research, and (d) knowledge creation within research. The arrows depict the proposed influences. Rather than research management influencing knowledge creation, or knowledge creation influencing research management, it is suggested that both are determined by the basic needs of research. That is, research is to some extent the master of the organization.

The Needs of Research	**The Management of Research**
• Generation of new discoveries: a vision of what <u>might</u> be possible rather than what <u>is</u> possible • Skills of enquiry and interpretation • Experimentation and 'trial and error' testing • Desired ends may be known but the means are less certain. Alternatively, the means may be known but the ends are less certain. • Learning from individual and team experiences • Acceptance of failure as part of the learning process • Inspiration and perhaps some serendipity Resulting in a prototype product or process.	• Matching scientific and technological expertise with strategic objectives • Flat and loose management structure • Steering (guiding) rather than control • Facilitation rather than process management • Encouragement rather than progress monitoring • Reward system based around the need for individual (and team) recognition within scientific peer groups • Management of 'understanding' as much as of 'prototype' production • Motivation by solving future problems
The Knowledge Needs of Research	**Knowledge Creation in Research**
• Future knowledge focus but without necessarily forgetting the past • Multidisciplinary knowledge and understanding of current scientific theories and facts, and basic technical skills • Flexible access to existing knowledge sources (scientific, technical, and commercial) of all forms • Knowledge and idea sharing within scientific communities of practice Resulting in the creation of new knowledge through knowledge exploration.	• 'Transdisciplinary Mode 1 Type' knowledge creation • Knowledge application based mostly on the needs of the individual researcher • Facilitation of individual knowledge acquisition and sharing mainly through knowledge networking • Promotion of flexible knowledge practices • Individual (and team) rewards through publishing, conferencing, and knowledge exploitation

FIGURE 6.5.1: THE PRACTICE OF PHARMACEUTICAL RESEARCH

The Needs of Research

Research is about creating something entirely new. It is about trying out ideas, about experimentation, and about questioning the givens. It involves skills of enquiry and creativity (Chapter 5, Section 5.3, page 162). It is risky with many false starts so that 'time lines' cannot be gauged and projects cannot be priced. Specific ends may be desired, but the means to achieve them are not necessarily known. Specific means may be known but the outcomes that they may yield will not always be clear (Jewkes *et al,* 1958, p.151). The final result will often depend upon the outcomes of a number of intermediate stages, and failure is part of a learning process (Chapter 5, Section 5.3.1, page 166; Section 5.3.3, page 175). Most importantly, research involves inspiration (Jewkes *et al,* 1958, p.223) and a vision of what *might* be possible rather than what *is* already possible. It is more 'future' driven (Leonard-Barton, 1995, p.33). People in research enjoy doing something new and solving future problems. Work may be hard, but it is also exciting. In these respects, research is similar to radical innovation (Morita *et al*, 1986, p.78).

The Management of Research

The needs of research mean that managing research is more about facilitation than about any particular process implementation. It is more about encouragement than about seeking strict accountability for the work pursued. It is more about *matching* strategic objectives and technological expertise. The management structure is flat and loose, and a great deal of flexibility is allowed, the expectation being that scientists will follow their own hunches (Chapter 5, Section 5.3.2, page 167). In effect, research units are steered (Burton *et al*, 1988, p.113) rather than controlled, since the path to completion is not known beforehand

(Jewkes *et al,* 1958, p.116). Strategy is seen as a 'guiding light' rather than an absolute target. Motivation is by providing challenging opportunities and creating an environment that encourages and supports experimentation (Chapter 5, Section 5.2.1, page 150).

The Knowledge Needs of Research

The needs of research necessarily determine the knowledge needs of research. Research is more a search for future knowledge than a search for the most efficient use of present knowledge. It is more about expanding knowledge boundaries than retaining knowledge within existing boundaries. It is essentially science and technology driven, and the knowledge used *is* predominantly of the 'Mode 1' type. Researchers undoubtedly use the knowledge that is available or accessible to them, but they do so in ways that are unique to the work that they are undertaking at the time (Chapter 5, Section 5.4.1, page 178). Since it is not possible to know before the work has begun exactly what knowledge will be needed or from whence that knowledge will come, researchers need access to a wide range of knowledge sources and in all possible ways.

Knowledge Creation in Research

Knowledge creation in research is about the exploration for new knowledge. It is science and technology led and is essentially a 'Mode 1' process.

Knowledge acquisition is important in research to the extent that it is neither practicable nor possible to do everything from scratch. Knowledge is acquired from the 'managed'

information in patents and scientific databases, but importantly the latest knowledge is 'acquired' by networking with other scientists and technicians. As mentioned above (page 260), occasionally knowledge acquisition may occur through hiring-in new expertise. Knowledge networking and hiring-in expertise arguably facilitates learning as well as information transfer. And, sharing early thoughts with others may not only help to consolidate those thoughts but may also add other perspectives and ideas (Chapter 5, Section 5.4.1, page 183).

Since it is only as a project progresses and new knowledge is created that the researcher becomes aware of what knowledge is needed next, rather than seeking to define an absolute set of knowledge processes necessary for research, it would seem that managers in research need to know how to promote and encourage flexible knowledge practices in general.

Although not a part of the knowledge creation process, knowledge exploitation through further development and technology out-licensing is an important way of acknowledging or rewarding staff for work done well.

Development

Knowledge creation in pharmaceutical development is knowledge creation carried out in the context of application. It is a transdisciplinary and transfunctional team process. Teams are managed by a project leader and they are required to meet preset targets as the development progresses. Knowledge creation in development is thus both directed towards a specific goal, and controlled to the extent that the inability to meet specific targets may seriously jeopardize project continuation. Control is possible within development because the processes and procedures used are largely fixed by regulatory requirements. Furthermore, knowledge creation in development is essentially about the application of existing knowledge rather than the creation of new knowledge by experimentation, so that, compared to research, there is a greater understanding of the science and technology involved. Project targets can therefore be set with a degree of (but not absolute) certainty (Jewkes *et al,* Chapter 2, Section 2.3.2, p.41).

Knowledge application in development is essentially through the auspices of team-working and is thus dependent upon the various members of the team working together and understanding each other's needs. This is not something that can be controlled, but is something that can perhaps be facilitated. Several interviewees stated that they do not have the luxury of being able to include specific role types within the teams that they form (Chapter 5, Section 5.3.2, page 170). We might question whether they have actually tried to do this. However, using one team to aid another was shown to facilitate team learning (Chapter 5, Section 5.4.2, page 191). This may be because there is an increased chance that the necessary role types are present in the combined teams, although it is perhaps more

likely that people will learn more readily from their peers if they know that they have already been through the process that they are about to enter.

Knowledge acquisition in development is both directed and controlled by the needs of the project, and usually occurs through technology and compound in-licensing agreements, and, particularly in the case of regulatory issues, though knowledge networking. Knowledge is shared as part of the team process, whether or not the team consists entirely of internal personnel or involves members from collaborating partners. To a large extent, the knowledge shared is then directed and controlled by the needs of the project. Knowledge may also be shared within the wider organizational community through the publication of project reviews, case reports, incident reports, and via company briefings. The idea is that others will learn the lessons of the past and build upon them, rather than repeat the same mistakes again. These latter forms of knowledge sharing are usually directed towards particular issues such as health and safety requirements, or process time or cost reduction possibilities. In many instances, the extent to which these lessons can be applied at a later date will depend upon either the ability to capture lessons devoid of context – something that would seem to be extremely difficult if not impossible to achieve – or the ability of individuals to recognize the relevance of past concepts in new contexts.

Figure 6.5.2 (next page) outlines, in a similar fashion to Figure 6.5.1, the practices of pharmaceutical development. In this case, and as indicated by the arrows, it is suggested that it is the organizational or management needs that largely determine the needs of development, the knowledge needs of development, and how knowledge is created within development. In short, development management directs knowledge creation within development. That is, the organization is the master of development.

The Needs of Development	**The Management of Development**
• Adaptation of existing discoveries • Transdisciplinary and transfunctional team process • Experimentation generally through standard procedures • Skills of analysis and an eye for detail • Acceptance of failure as part of the learning process • Learning from team experiences • Ends and means usually known with some certainty • Present focus: making the vision possible Resulting in the creation of a regulated and approved product or process.	• Matching research discoveries with market needs • Managing the people and managing the process: matrix management of multifunction project teams; project monitoring and review strictly to milestone commitments • Management of risk and management of attrition • Reward system based around team learning as well as results • Often the management of collaboration • Motivation by task completion, by combining the vision of the future with the reality of the present
The Knowledge Needs of Development	**Knowledge Creation in Development**
• Present and past knowledge focus but with an eye to the future • Understanding of current scientific theories and facts, basic technical skills, and commercial factors, particularly regulatory requirements, of relevance to the task in hand • Access to existing information sources (scientific, technical, intellectual property, regulatory, commercial) in fairly standard ways • Extensive knowledge and idea sharing within project teams Resulting in the creation of new knowledge largely through the exploitation of existing knowledge.	• A Coordinated Mode 2 type knowledge creation • Active Project Management • Knowledge acquisition mainly through technology in-licensing and formal collaborative ventures • Project knowledge sharing and application through the auspices of team working • Regulatory knowledge acquisition and trust building through knowledge networking • Team rewards as the result of project completion and team learning

FIGURE 6.5.2: THE PRACTICE OF PHARMACEUTICAL DEVELOPMENT

The Management of Development

The management of development is about modifying research discoveries to meet business needs, about adapting discoveries as the environment changes, about team working and, especially in the pharmaceutical industry, about managing attrition. Since development is often carried out in collaboration with others, the management of development is also about the management of collaborations and alliances, and most specifically about uniting the whole workforce (internal and external) behind the active project. Matrix management enables people from the various functions to be brought together in project teams (Chapter 5, Section 5.3.2, page 169) and project management tools are employed to track progress against milestone commitments, to flag problems as they occur, to undertake remedial action at the earliest possible time, and, importantly, to share thoughts and ideas throughout the organization (Chapter 5, Section 5.3.2, page 172). A managed approach is possible because development is more certain than research in that the desired 'ends' and 'means' are usually known (Chapter 5, Section 5.3.2, page 169).

People in development are motivated by the satisfaction of bringing a product to market. They are also interested in ensuring product integrity (safety and efficacy) and in solving current problems (Chapter 5, Section 5.4.2, page 188). They accept that work needs to be ordered, but, at the same time, it has to be seen to be worthwhile. Because attrition rates are high, reward systems need not only to be based upon final results but also upon what has been learnt in the process and whether that learning has been shared with others (Chapter 5, Section 5.3.3, page 175).

The Needs of Development

Development is about using the results of research to develop a commercially viable product or process (Chapter 5, Section 5.4.2, page 188). It requires a transdisciplinary, a transfunctional, and sometimes a transorganizational team view (Section 6.3, page 219). But, importantly, it is about adopting a 'managed' approach in order to gain regulatory approval (Chapter 5, Section 5.3.2, page 168). It is thus more present and past driven. Nevertheless there are still uncertainties concerning drug efficacy and side effects in humans that mean that skills of analysis and an eye for detail are requirements that are crucial in order to understand the lessons that may be important for the future. Development is thus similar to incremental innovation (Lorenz, 1990, p.119).

The Knowledge Needs of Development

Pharmaceutical development requires strict adherence to regulatory issues. In addition, the product and process data generated during development will need to be readily available in a format suitable for regulatory approval. Past and present project knowledge, and present and possible future regulatory knowledge, and the lessons that may be learnt from that knowledge are consequently crucial knowledge requirements in development (Chapter 5, Section 5.4.2, page 188). Databases are useful for storing, collating and combining existing scientific and technical, information (and to the knowledgeable user, the knowledge behind that information). 'Experimental results' databases and electronic notebooks are useful for storing information (and the knowledge behind that information) for regulatory purposes. 'Expert resources' databases allow contact to be made with knowledgeable individuals. 'Stories' and 'lessons learnt' databases can prove useful in

helping workers understand the lessons of the past. And, project management tools and techniques provide transparency and focus for knowledge creation activities (Chapter 5, Section 5.4.2, page 202).

Knowledge Creation in Development

Knowledge creation in development is a structured, team-based process that seeks to exploit the existing knowledge of research with the development experiences of the past, in order to achieve the regulatory and commercial needs of the present and near future (Chapter 5, Section 5.4.2, page 188). It is knowledge creation in the context of application and is essentially a 'Mode 2' process.

External knowledge acquisition is typically via in-licensing agreements, although networking with the regulatory authorities does provide the information needed for specific approval issues. Formal collaborations are particularly important for gaining, sharing, and exploiting project-related knowledge that might otherwise be deemed secret to *outsiders* (Chapter 5, Section 5.4.2, page 200). Personal knowledge networking is important for sharing and expanding upon general rather than project related knowledge (Chapter 5, Section 5.4.2, page 198).

Team working is by necessity transdisciplinary and transfunctional and may be transorganizational. And working in this way enables the knowledge of all the collaborating partners to be applied to the problem in hand (Chapter 5, Section 5.4.2, page 197).

6.6 The Most Important Factors in Managing R&D

Commercial Viability *(Chapter 5, Section 5.2.1, page 150)*

Commercial viability is ultimately essential for the continuation of any business enterprise. However, until recently, pharmaceutical research was to a significant extent divorced from the commercial end of the organization. Commercial viability was the province of pharmaceutical development, not pharmaceutical research. The aim of research was to discover the new compounds, materials and technologies that had the potential to cure disease. There was an implicit need on the researcher's part to understand how these materials and technologies functioned and how they might be useful in meeting the future needs of the organization, but there was little need to understand the day-to-day operations of the existing needs of the business. Research costs may have been significant, development costs may have been high, but profits were huge. When questions were asked about these profits, the pharmaceutical companies pointed to the high costs of R&D. These costs were undoubtedly true, but what was perhaps more important was that it was not possible to understand whether or not they were always necessary. There was much that was unknown about the science and technology involved.

Although complete understanding is not yet available today, the advent of biotechnology and particularly gene technology has led to a much greater understanding of how living systems succumb to disease and consequently how disease might be cured. This leads to the possibility of more focused research and more accountability in research. Research, like development, can then be more easily adjusted to the commercial needs of the

business, and questions about profits can be justified by the specific work carried out. Research becomes more business orientated, and commercial viability is important from the beginning of the process. The problem with this change is that there is still much that is unknown about the science involved. When commercial viability is the requirement, it is the safer and largely understood options that are usually adopted and progressed. The less understood and therefore more risky options are largely ignored. The tragedy is that these more risky options may ultimately yield a far better result for both the company and the customer (patient) than might initially be thought to be the case. Whilst there are undoubtedly arguments for commercial viability in development, like Pearson remarked, 'It would be a pity if companies no longer undertook any exploratory research at all' (Pearson, 1991, p.21). Most of the interviewees in this study would probably agree with this statement; they do, after all, have a scientific background.

When research and development activities are separated there is perhaps the implication that, to a degree, exploration and educated risk taking is implied or is allowed, at least in research. Whether this will remain so if commercial viability is allowed to dominate research as well as development is perhaps questionable. Where will the radically new ideas come from if research and development is always carried out in the context of commercial viability? What about the increased understanding that comes about from a consideration of the previously unexplored? Should this be the sole province of the universities and other research institutes? Can these research organizations themselves continue to advance scientific understanding in this way when their financial resources are limited (Chapter 3, Section 3.5, page 123) and they are continually required to account for their work in the context of a nation's current rather than its possible future needs?

A Clear Focus, a Flexible Approach and a Culture of Experimentation in Research

(Chapter 5, Section 5.2.1, page 150)

When management is by guidance rather than by controlled direction it is important that the overall purpose is clear. Experimentation can yield a number of alternative paths that *may* be taken, a clear focus guides the researcher towards the path that *should* be taken. A clear focus provides the 'control' for what work is to be carried out, how it is to be carried out, and why it is being carried out. A clear focus thus encourages efficiency in the research process. A clear focus will also help to determine when a particular research route needs to be abandoned.

Working within a multidisciplinary or transdisciplinary environment means that the results that one researcher obtains may affect the work of other researchers in other disciplines, or, alternatively, the findings of research may mean that the existing commercial requirements can no longer be met. A flexible approach is then required to accommodate these possible conflicting requirements.

When intermediate outcomes are inherently uncertain it may perhaps be assumed that flexibility is a 'given'. However, when a particular approach is passionately believed (rather than known) to be the right approach, the determination to succeed with that approach can sometimes be seen as inflexibility. What is interesting is that belief and determination can sometimes succeed where existing knowledge would suggest that it should not. Flexibility is then needed on the part of management to allow researchers to pursue their beliefs. To varying degrees, this is something that does appear to happen in UK pharmaceutical research.

Experimentation is risky since the outcome is uncertain. If it were not, there would be no point in carrying out the experiment in the first place. Risk implies the chance of failure. Although researchers may inherently be risk takers, companies are rarely so. It takes confidence to go against the normal rules. Failure can erode that confidence, especially when it is success alone that is rewarded. All of the interviewees in this study recognized the importance of supporting their staff through the failures that would inevitably occur when experimentation was part of the process. What was important was not that failure had occurred, but that failure brought learning and understanding and new knowledge.

Teams of People, a Clear Project Plan, and Buy-in in Development

(Chapter 5, Section 5.2.1, page 151)

Pharmaceutical development is about team working. It is about the various disciplines and functions working together to progress and produce a product or process suitable for its context of use. Teams are typically put together on the basis of technical (scientific, technological or commercial) ability and staff availability. It was simply not possible to also put teams together with the most appropriate personality characteristics. Instead, what appears to be encouraged in most of the companies in this study is an environment of cooperation and facilitation throughout the organization as a whole. Encouraging the whole organization to support development activities is one way that arguably overcomes any personality deficits within the actual development teams themselves.

The more certain 'ends' and 'means' in development support the provision of a clear project plan. The provision of such a plan encourages discussion both within and across

the various departments involved, and, by making explicit some of the underlying functional assumptions, contributes to organizational understanding. It focuses attention on the likely financial and resource costs of the project, and the projected time requirements of the various activities involved. It gives transparency to the process and assists in subsequent accountability and decision making. Notwithstanding the existence of a project manager, the process relies on a high degree of self-management, it clarifies, to all, what needs to be done, when it needs to be done, and by whom it should be done.

However, a clear project plan is only useful if it is feasible. The incorporation of unrealistic targets and time scales can lead to de-motivation rather than the super-human efforts predicted by 'stretch'. As pointed out by several of the participants in this present study, it is the professional developers who have the greater understanding of what can be done, not the managers. Their participation in the drawing up of the plan is therefore crucial, and goes a long way to ensuring their 'buy-in' to the decisions made

(Chapter 5, Section 5.3.2, page 172).

Communication

(Chapter 5, Section 5.2.1 page 152)

Because effective communication is dependent upon there being the need for some shared understanding between the communicating parties, it is not infrequently assumed that communication can be a problem between the different functional groups that make up the organization or extended organization. Each group may have its own 'language' and may adopt a different perspective on what is required and how it should be achieved. Although

different views undoubtedly do occur, it is through further communication that these views can be declared and shared. What is perhaps forgotten is that despite our variety we are all human beings, and thus have some understanding in common.

It is interesting that both researchers involved in transdisciplinary Mode 1 type working (who often work separately from the other functions of the firm) and developers involved in coordinated Mode 2 type working (where the functions work together) emphasized that communication was important. In research, communication is necessary to give direction to the activities undertaken, to obtain and learn from the knowledge available elsewhere, and to promote the results of research to others. In development, communication is more about the sharing of knowledge within the project team in order to arrive at a unified approach to the task in hand.

When the shared understanding that develops between life-time colleagues is not a possibility, it is perhaps hardly surprising that communication is thought to be important. How else can knowledge be acquired, shared and used? The problem is that, as shown in Chapter 3, Section 3.3, there is more that needs to be acquired, shared and used than the explicit knowledge that is normally associated with the spoken word.

6.7 Conclusion to the Chapter

The complexity of pharmaceutical R&D militates against the efficacy of models based on overly simplistic assumptions. Indeed, the problems associated with such assumptions can generate more questions than answers. As this chapter has demonstrated, challenging questions arise from propositions about successive generations of R&D, Mode 1 and Mode 2 knowledge production, Nonaka and Takeuchi's notion of tacit-explicit knowledge conversion, and Cook and Brown's case for 'bridging epistemologies'. However, Polanyi's original concept of tacit knowing has stood the test of time: half a century after he developed his concept of 'tacit knowing', the arguments remain fresh and relevant.

By comparing the basic needs, the management processes, the knowledge needs, and the knowledge creation processes in pharmaceutical research and pharmaceutical development, Section 6.5 concluded that it is the basic needs of research that largely determine what knowledge is needed, how knowledge is created, and the management practices in research, whereas it is the business or management practices that largely determine the needs of development, the knowledge needs of development, and how knowledge is created in development. Thus, whilst an organization may wish to pursue strategies that foster business integration (third generation R&D) and collaborative working (fourth generation R&D), is it wise that it do so throughout the entire range of its activities? Certainly, successful companies operating in the UK pharmaceutical industry continue to adopt research (as opposed to development) strategies akin to a science/ technology push approach (first generation R&D). Might it not be wise for other companies wishing to carry out research (as opposed to development) to do likewise?

Similarly, whilst Mode 2 working within the context of application might be the best way to bring the various functions and departments together during development, is this the best approach to adopt in research? To the extent that research is largely science-based and inherently individualistic, it would be imprudent to ignore the potential contribution of Mode 1 knowledge production to competitive innovation in the pharmaceutical and similarly research-intensive industries. Indeed, many of the interviewees who contributed to this study viewed such working as important for sourcing new ideas and seeding new R&D trajectories. They did not appear to agree that the transient clusters of Mode 2 working would 'increasingly produce the specialist knowledge that will characterize the knowledge industries of the future' (Gibbons *et al*, Chapter 3, Section 3.4.1, page 106). In fact, the reverse would seem to be implied. Yet, the increasing need for proven commercial viability even in corporate research may alter the balance of power in favour of Mode 2 knowledge production. From the point of view of applying managerial techniques to discovery, this might be seen as progress: it avoids mistakes. But, as Einstein is often purported to have said: 'A person who never made a mistake, never tried anything new'. Ultimately, innovation involves the exploitation of novelty.

The different perspectives of research and development are reflected in the factors thought by the participants of the empirical research to be those most important in managing R&D (Section 6.6). For example, most notably, it was thought that not only should organizations be commercially aware (cf. development) but they should also participate in the process of exploration (cf. research). However, whilst considering the differing requirements of research and of development, there is also the need to ensure that both of these activities are seen as part of the wider organizational process to which they each

contribute. Hence, communication, in the widest sense of the word, becomes a key requirement for success.

Clearly, the answer to any question is dependent upon the assumptions made and the perspectives adopted. Whilst it is difficult to reconcile the knowledge conversion processes suggested by Nonaka and Takeuchi with the fieldwork reported in this thesis, some of their concepts reflect relevant issues associated with communicating, learning and innovating. Specifically, knowledge sharing through *socialization* and *externalization*, and knowledge acquisition through *combination* and *internalization* are processes that can be envisaged in R&D. The proviso is that such processes do not involve the conversion of one form of knowledge into a different form of knowledge.

Although Cook and Brown's focus on 'knowing as part of action' circumvents some of the difficulties associated with Nonaka and Takeuchi's concept of tacit-explicit knowledge conversion, it is not easy to relate actual practice to their claim that tacit knowledge and explicit knowledge possessed by individuals and groups represent unambiguously distinct categories of knowledge. Nevertheless, the application of Cook and Brown's model to the various activities that make up the R&D process graphically highlights the intricacies and differences between knowledge creation in research and knowledge creation in development. In so doing, it adds to the debate about how these two organizational activities might best be managed. For example, where individual knowledge is the predominant need of the process or activity of interest, there would appear to be little point in promoting team working. Where group knowledge is an essential requirement of the activity or process of interest, the promotion of individualism would appear to be counterproductive.

Finally, the chapter has demonstrated ways in which Polanyi's concept of tacit knowing remains both credible and useful. Polanyi points to a coherent interpretation of the complex and inherently personal nature of what is commonly referred to as 'knowledge`. He argues that the quest for knowing implies a personal commitment to seeking a deeper understanding of an underlying 'reality'. And, his proposition of personal acts of tacit knowing that account for the actions that we each take and the way in which we each learn from others and come to understand the world around us, would appear to offer a distinct advantage over those models that advocate the commodification of 'tacit knowledge' and 'explicit knowledge'. Specifically, the commodification of knowledge implies that knowledge is a 'thing' that is separate from the knowing subject - hence, the people who know how to 'do things' in practice are effectively written out of the picture. Instead, Polanyi's concept of 'personal knowledge' affords a centre-of-stage role to the people who know how to think and act in any given context. Although the idea that people (*persons)* know things might sound like a statement of the obvious, traditional expectations about scientific objectivity, along with related perspectives based on the 'commodification' of tacit knowledge and explicit knowledge 'objects', effectively exclude the role of people. Ultimately, better understanding the organizational capacity to translate pharmaceutical R&D into competitive gains and losses depends on better understanding the people who know how to make the differences that translate into competitive gains and losses. In a world with no people, nobody would know anything.

In drawing this thesis to a close, the next chapter, Chapter 7, now summarizes and discusses the conclusions of this present study, the major contributions to knowledge, and the major limitations of and some possible extensions to the work reported herein.

7 CONCLUSION

7.1 The Major Conclusions

This thesis set out to look at knowledge creation in corporate R&D, the assumption being that, in the present knowledge-based economy, effective knowledge creation would be the primary driver for successful corporate as well as academic R&D. However, in pursuing this objective, it was found necessary to look into the general practices of R&D departments and consider relevant aspects of the context of knowledge creation, rather than concentrate on knowledge creation *per se*. This was because, typically, R&D workers and managers – the primary sources of the information upon which this thesis is based – do not perceive themselves to be driven by the pursuit of 'knowledge creation' as an end in itself. Hence, in employing knowledge creation as a conceptual vehicle for making sense of a wide diversity of R&D practices associated with competitive innovation, the findings and the conclusions in this thesis have, of necessity, been grounded in the approaches, the practices, and the general knowledge processes employed in corporate R&D.

Approaching the study of knowledge creation in this way, led to four specific aims of the research:

1. To identify the general approaches and practices employed within corporate R&D and the possible influences these approaches and practices might have upon the knowledge creation process.
2. To determine the extent to which Gibbons and co-workers' (1994) modes of knowledge production might be important to making sense of contemporary R&D.

3. To examine the extent to which the existing models of organizational knowledge creation might be useful in interpreting knowledge creation within an R&D context.
4. To look at the way in which knowledge is created within UK-based pharmaceutical R&D as a basis for identifying more general insights into the practice of corporate R&D.

In respect of the first aim of the research, Chapter 2 identified five strategic approaches to corporate R&D, the R&D Generations, and outlined conceptual interpretations of the practice of R&D that had been reported in the earlier literature. At the same time, the chapter suggested the types of knowledge and the knowledge processes employed in each instance. In attempting to deconstruct some of the complexity associated with the inter-relationship between the practice of corporate R&D and the context within which that R&D takes place, it became apparent that the higher level generalizations about R&D Generations masked the complexities of micro-level R&D processes: complex organizations create knowledge in a variety of ways, and many different nested and overlapping interest groups may exert their respective influences over the way in which R&D is practiced. While the concept of R&D Generations may help to explain some of the observed variations in corporate R&D strategy, attention to micro-level practices revealed a more complicated picture.

The nature of micro-level processes was indicated by the findings of Chapter 6, Section 6.2. Specifically, what was deemed appropriate in terms of strategy varied according to whether the focal activity was *research* or *development*. On the one hand, research remained largely free from corporate interference: creativity was aligned with the autonomy of researchers in a manner that reflected the 'traditional' first generation

science/technology-led approach. On the other hand, development was sensitive to the edicts of corporate strategy: it typically reflected themes embodied in third generation 'business integration' and fourth generation 'external collaboration' models. Whereas research relied heavily on the power of fluid and flexible practices mediated by the individual experimental scientist or technologist, development adopted the more managed practices required by the business-focused transfunctional project team. In other words, research strategies were shaped by the community of researchers, while the interests of the organizational managers tended to have a more direct influence on development strategies.

In relation to the second aim of the research, Chapter 3, Section 3.4.1, outlined the principal propositions of Michael Gibbons and his co-workers, and Chapter 6, Section 6.3, discussed this work in relation to the findings of this present study. In particular, it was shown that neither pharmaceutical research nor pharmaceutical development corresponded exactly with either Mode 1 knowledge production or Mode 2 knowledge production as proposed by Gibbons and his colleagues. In addition, although the distinction between Mode 1 and Mode 2 sounds simple enough in the abstract, research practice in the pharmaceutical industry highlights the difference between the *production of knowledge* and labels that relate to *knowledge outputs*. Although this might sound like an unduly subtle point, it has significant implications.

Both the *production* of Mode 1 knowledge and the *outputs* that it produces are commonly referred to as 'science'. That is to say, the process of conducting basic scientific research, according to the scientific method, is assumed to produce scientific outputs, which equate to objective knowledge. However, the tendency to equate the *process of knowledge production* with *knowledge outputs* can contribute to confusion. Although Mode 1

knowledge outputs might be objective and value-free, the processes that produce those outputs are subject to political, economic and social influences that variously enable and constrain the research agenda. Rather than being a purely science/technology-led process. pharmaceutical research ultimately relies upon a commercial evaluation of any candidate drug or therapy that might be discovered. Accordingly, pharmaceutical research might better be termed a transdisciplinary Mode 1 type activity: basic research that is shaped by interaction between the scientific disciplines and influenced by 'supply-side' factors associated with the 'context of knowledge production'.

In contrast, Mode 2 knowledge production does not produce a homogeneous body of knowledge (in the sense that science could be described as a homogenous body of knowledge). On the contrary, the outputs of Mode 2 knowledge production are heterogeneous: different people learn different things as a result of their participation in the production of knowledge. Hence, although it might be helpful to talk about the *process* of Mode 2 knowledge production (for example, in terms of the joint efforts of different practitioners who contribute to a specific area of problem-solving activity), each participant constructs his or her personal interpretation of the learning experience. Mode 2 knowledge production does not produce disembodied Mode 2 'knowledge outputs' that mirror the objective status of Mode 1 scientific outputs: the outputs of Mode 2 knowledge production are context-specific and personal. From a managerial point of view, the challenge is to recognize and coordinate appropriate aspects of the Mode 2 knowledge-producing process. On this account, pharmaceutical development might be classed as a *coordinated* Mode 2 type activity. Managers have to coordinate different aspects of personal knowledge possessed by participants who collectively comprise what Gibbons and his colleagues refer to as 'the context of application'.

Corporate pharmaceutical R&D relies on research and development working in tandem: to the extent that each needs the other, it is difficult to sustain the idea that one is more important than the other. While there are significant differences between the two activities, they are bound together in a complementary relationship. Thus, the proposal by Gibbons and his co-workers that Mode 2 working would come to predominate over Mode 1 working (Chapter 3, Section 3.4.1) has not been confirmed here. Although many areas of economic activity, including research-intensive sectors such as the pharmaceutical industry, are indeed becoming more concerned with addressing 'user needs' associated with the 'context of application', significant breakthroughs in basic research can reveal new avenues of commercial possibilities. In the case of the pharmaceutical industry, major breakthroughs can reshape the commercial landscape and thereby focus more attention on transdisciplinary Mode 1 knowledge production.

In attempting to answer the third aim of the research, Chapter 3, Sections 3.4.2 to 3.4.4, described the main points of the knowledge creation models proposed by Nonaka and Takeuchi (1995), Cook and Brown (1999), and Polanyi (1966); and Chapter 6, Sections 6.4.1 to 6.4.3 outlined the relevance of these models as they applied to corporate pharmaceutical R&D. In particular, Chapter 6, Section 6.4.1, outlined how Nonaka and Takeuchi's (1995) model suffers on several counts. First, it relies on four processes which define conversions between four unique forms of knowledge (tacit and explicit, possessed by individuals and groups), forms of knowledge which by their very definition defy the possibility of conversion. Second, although making sense of Nonaka and Takeuchi's model is made easier if we avoid their use of the verb 'to convert' as a way of describing the process in which one unique form of knowledge is ostensibly 'converted' into an entirely different form of knowledge, their remaining implication that knowledge is

somehow diminished in the 'conversion' process fails to accommodate the idea that knowledge is not diminished by its use. For, if one person tells another something useful, the second person's knowledge may be increased but the first person's knowledge is neither diminished nor converted into something else: it was merely *used* to support a knowledge creating 'conversation'. Third, the findings of this present study would suggest that the knowledge used within R&D would not seem to be easily separable into the four forms of knowledge suggested by Nonaka and Takeuchi. For example, experimental design in research and project design in development rely upon what some might refer to as the 'tacit' knowledge of intuition as well as the 'explicit' knowledge of established wisdom. Although the abstract concept of a distinction between tacit knowledge and explicit knowledge, possessed by individuals and groups, might sound straightforward, practical examples suggest that it can be difficult to see where one category of knowledge stops and another starts. Fourth, in line with McAdam and McCreedy's comments noted in Chapter 3, Section 3.4.2, it would indeed seem that knowledge creation in research and in development is *not* the systematic and cyclic process proposed by Nonaka and Takeuchi, since, at least within the companies of this present study, much knowledge is created by direct *interaction at the same* ontological level, and *more than one form of knowledge may be used at the same time* to create new knowledge. In parallel with, what might be seen as Nonaka and Takeuchi's 'Jacob's ladder' or *vertical* approach, which ascends from individual knowledge to universal knowledge, there are *horizontal* influences on the processes by which the 'spiral' of knowledge creation ascends to higher ontological levels.

Nevertheless, the findings of this present study would suggest that processes similar to socialization, externalization, combination and internalization do play a part in corporate

R&D. The proviso is that these processes do not involve the conversion (or even the use) of any one specific form of knowledge to produce another specific form of knowledge. Thus, the s*ocialization* that occurs through the use of personal knowledge in networking and organizational team working is crucial to the acquisition and sharing of the knowledge necessary for the activities of both research and development. The *externalization* of knowledge that results through the use of formal organizational statements and formal and informal project review meetings is crucial in clarifying objectives and signalling problems. The *combination* of knowledge from the various functional departments that make up the organization is critical to ensure the commercial viability necessary for development and the guidance needed in research. And, with the *internalization* of new knowledge comes the possibility of a deeper understanding of the reality with which we are each confronted in our everyday lives and, thus, the possibility of new ideas and solutions.

By accepting Nonaka and Takeuchi's use of tacit knowledge and explicit knowledge, of the individual and group varieties, Cook and Brown's Pluralist Framework also suffers on the count that the knowledge used within R&D would not seem to be easily separable into these four unique forms of knowledge. Nevertheless, their framework does give one explanation of how new knowledge might come about. It comes about through the use of knowledge as a tool of productive enquiry as part of our dynamic interaction with the things of the social and physical world (Cook and Brown, Chapter 3, Section 3.4.3, page 113). That is, new knowledge comes about because of the actions we take (physical or mental) and the interpretations we make, not because of the conversion of one form of knowledge into another.

However, the framework in itself gives little idea of which forms of knowledge and knowing are involved within any particular context, at any particular time, or for any particular purpose. What is needed is a coupling of the framework with the basic activities involved in the particular context of interest. The couplings for the pharmaceutical research and pharmaceutical development processes, as indicated by the findings of this present study, were shown in Chapter 6, Section 6.4.2 (respectively, Figure 6.4.3, page 243, and Figure 6.4.4, page 246). These couplings graphically display the differences between knowledge creation in research and knowledge creation in development – research is clearly seen to be largely, but not wholly, an individual process, whilst development is clearly seen to be largely, but not wholly, a group process - but they also emphasize the fact that, overall, both processes employ all four forms of knowledge represented by the explicit-tacit and individual-collective dimensions. That is, intuition (individual tacit knowledge) and shared ways of working (group tacit knowledge) are as important as individual explicit knowledge and group explicit knowledge in both research and development, although the extent to which these different knowledge forms are used and the purposes for which they are used vary depending upon which basic activity is being pursued and whether research or development is the process.

In providing a graphical description of the knowledge creation process in a particular context, the coupled model has the potential to improve the understanding of why particular processes need to be managed or practiced in a particular way. For example, when individual knowledge is the predominant need of the activity concerned, there would appear to be little point in promoting team working. When there is the need for efficient and effective use of 'collective' knowledge, the promotion of individualism would seem to be counter-productive. Whilst many companies will inherently pursue their activities in

ways that appear (and in many cases are) appropriate for success, the coupled model offers an additional way of evaluating the efficiencies and practicalities of the approaches and practices being adopted.

Nevertheless, by adopting Polanyi's view that all knowledge is inherently personal and relies upon a tacit dimension, it becomes easier to relate conceptual views of knowing to observed practices. Thus, Chapter 6, Section 6.4.3, suggested how Polanyi's approach can be used to show us how knowledge creation is the result of the particular personal and purposeful acts of tacit knowing of the people involved in the pursuit of a particular objective – acts of tacit knowing which rely on the assumptions made and the perspectives adopted, and which account for the lessons learnt and the way in which these individuals work with each other.

In deciding between the various models of knowledge creation described above, it should perhaps be added that any theoretical model is only as useful as the predictions it is able to make (Kerlinger, 1969, p.12). All models are simplifications, but some models are useful. In this respect, it is perhaps Polanyi's approach that offers us more than the models of either Nonaka and Takeuchi or Cook and Brown. For example, Nonaka and Takeuchi's presumption that knowledge creation is a vertical process, which ascends from the individual to higher ontological levels, is inappropriate to Western R&D environments that rely heavily on horizontal networking. And, whilst Cook and Brown's model coupled with the activities of the process involved might provide a greater understanding of what is already known, its predictive potential would appear low. In addition, its sheer complexity, which relies on the view that knowledge comes in no less than four distinct objectifiable forms (tacit and explicit, possessed by individuals and groups) associated

with the category (epistemology) 'knowledge as possession', along with a separate category (epistemology) associated with 'knowing as action', together with the concept of bridging epistemologies, militates against its easy application to actual practices.

If, however, we accept Polanyi's comparatively simple premise that new knowledge is created from the existing knowledge base as the result of personal acts of tacit knowing, then, in order for new organizational knowledge to be created within any environment, the best approach to take is to actively involve the people with the relevant existing knowledge in that knowledge creation process. Thus, we might predict that research may be left to the scientists and technicians, whilst development should be a joint operation involving staff from the research, development, and commercial functions. That is, rather than trying to transfer knowledge between departments, the best approach is, as observed in this current study, to accommodate transdisciplinary Mode 1 type working in research and transfunctional Mode 2 type working in development. In addition, the creation of knowledge through personal acts of tacit knowing implies that, even in the scientific field of research and development, knowledge creation may not necessarily be the purely objective activity it is often assumed to be. As evidence of this, the interviewees participating in this present investigation recognized that intuition plays an important part in R&D to the extent that significant discoveries are often made by individuals working counter to what logic and current theory would dictate. As Polanyi originally stated, 'The pursuit of discovery is based upon a vision of what might be, a vision which is simply our meaningful integration of the parts of the complex entity we are trying to understand' (Polanyi and Prosch, 1975, p.54). And, 'The discovery which satisfies this pursuit is still sustained by the same vision. It claims to have made contact with reality: a reality, which

being real, may yet reveal itself to future eyes in an indefinite range of unexpected manifestations' (Polanyi, 1966, p.24).

In attempting to understand why things are as they are, and thus identify some general insights into the practice of R&D – the fourth aim of the research – Chapter 6, Section 6.5, advanced the suggestion that it is the needs of research that necessarily determine what knowledge is needed, how knowledge is created, and the management practices in research; whereas it is the needs of the organization that necessarily determine the needs of development, the knowledge needs of development, and how knowledge is created in development. The explanation for the differences between research and development was based on the observation that research is about the search for something new – exploration in pursuit of new knowledge – whilst development is about the adaptation of something that already exists – exploitation of existing knowledge. The implication is that, as observed within this present study, the activities of research should be separated from those of development.

Whether or not research should be separated from development has been an argument that has existed for many years – certainly it was an ongoing discussion during the time that the present author was herself involved in such activities. On balance, this present author's feelings were that such activities should not be separated, on the grounds that this might encourage elitism, and result in the formation of isolated collectives or cliques within the organization which would be counter-productive to R&D success. However, the fact that the two activities of research and development are grounded on the use of substantially different knowledge creation processes suggests a conceptual division: the two activities imply different types of practices. Yet, the relationship between these practices is

complementary, and paying undue attention to one dimension of a complementary relationship can undermine awareness of the way in which the two dimensions work together as a pair.

Certainly, it is clear that separating the work of research from that of development should not mean separating researchers from developers. Indeed, researchers ultimately need knowledge of the market place to ensure that the work that they are undertaking is directed accordingly, and that the results of their research can be focused towards any needs that arise. And, developers need to understand the newly found knowledge of the researchers in order to apply this knowledge in the most effective way towards the specific ends required. Effective connections between research, development and the evolution of user needs rely on the intelligent cooperation of colleagues, supported by mutual understanding among practitioners concerned with each of the respective processes. The success attributed to pharmaceutical R&D in the United Kingdom might perhaps, in part, be attributed to the fact that the sharing of information, the knowledge behind that information, and the understanding that results is widespread throughout the majority of organizations studied, and indeed throughout the industry as a whole. It occurs through informal personal networking, through formal research and project review meetings and presentations, and through collaborative 'team working' in the widest sense.

The different requirements of research and development are reflected in the factors identified by the participants of the empirical study upon which this thesis is based as being those most important in managing contemporary corporate R&D. Thus, Chapter 6, Section 6.6, showed us that whilst commercial viability is strategically important in business driven development, a degree of exploration is fundamental to science/technology

led research. And, from a management perspective, whilst teams of people, a clear project plan, and buy-in to that plan are specific requirements of development; a clear focus, a flexible approach, and a culture of experimentation are needed in research. At the same time, given the 'natural' separation of the two activities of research and development, communication throughout the organization and extended organization is a key requirement.

Based upon the conclusions outlined above, the next section of this chapter, Section 7.2, turns to the specific contributions to knowledge claimed by this thesis.

7.2 Contributions to Knowledge

A knowledge perspective was initially adopted for this present work because it seemed to offer a useful way of addressing the processes by which people in pharmaceutical companies know how to 'do things' associated with research, development and the pursuit of competitive success. However, a consequence of this way of working is that this thesis has been able to offer a contribution to existing knowledge that represents a marriage of ideas from the fields of R&D Management, Knowledge Management, and Innovation Management. In particular, the thesis has shown the similarities between Knowledge Management's Mode 1 working and R&D Management's first generation R&D; and between Knowledge Management's Mode 2 working and R&D Management's later R&D generations. It has also shown the similarities between the practice of research and Innovation Management's radical innovation, and the practice of development and Innovation Management's incremental innovation.

Furthermore, by evaluating Knowledge Management's knowledge creation models in the light of research and development practices, the thesis has perhaps provided a deeper understanding of these models and the possibilities of their application. It has evaluated and upheld the faults associated with Nonaka and Takeuchi's widely quoted knowledge creation and conversion cycle: namely, that knowledge creation is a more complicated and convoluted process than that proposed (McAdam and McCreedy, 1999); that knowledge cannot be converted into a common currency and moved from one context to the other; and, hence, that knowledge creation cannot be a knowledge conversion process (Ray and Little, 2001). It has questioned Cook and Brown's hypotheses that, first, explicit knowledge and tacit knowledge of the individual and group are *four unique forms* of

knowledge, and, second, that knowledge creation is a *generative dance* between 'knowledge used in action' and 'knowing as part of action'. Yet, the coupling of Cook and Brown's basic framework with the specific activities involved in a particular organizational process, nevertheless, does yield a graphical representation of that process that shows clearly the implications for how that process might be managed. However, importantly, it is by applying Polanyi's philosophical arguments to the practice of research and development that this thesis perhaps offers a more significant contribution. For, if we accept that all knowledge is created from the existing knowledge base as the result of personal acts of tacit knowing, then, in addition to the needs of the business, it is to the needs of the people involved that we must turn our attention.

Finally, by adopting a knowledge perspective and concentrating on practices at the task level, this thesis has perhaps more clearly than hitherto demonstrated the fundamental differences between research and development, and in so doing has given a more comprehensive explanation for why these two activities should be carried out separately but not separate from each other. In so far as the pharmaceutical industry is concerned, the needs of the activity being pursued would appear to be as important if not more important than any particular strategy that might be advocated.

An emphasis on 'knowledge' may, however, have overshadowed some of the other issues surrounding the management and practice of corporate R&D. At the same time, this thesis is based upon the findings from only one industry within the United Kingdom. The same findings may not be applicable elsewhere. The final section of this chapter, and of this thesis, briefly discusses these limitations of the present study and suggests some possible extensions to the work reported herein.

7.3 The Major Limitations of and some Extensions to the Research

The conclusions drawn within this thesis have been based upon the findings from one particular industry. This does not necessarily mean that the same conclusions will hold for other industries. For example, this thesis has emphasized the importance of science/ technology leadership in research and business integration in development. The pharmaceutical industry is an industry in which both science and technology are important: it is the increased understanding of the underlying science that drives the improvements in appropriateness and effectiveness of modern therapies; and it is the advances in technology that enable the increased efficiencies required for continued commercial viability in an increasingly competitive business sector. Although a reliance on basic research distinguishes the pharmaceutical industry from competitive innovation in low-technology sectors, the knowledge-based approach developed here, nevertheless, embodies scope for application elsewhere. Few industries are immune from the changing pattern of constraints and opportunities associated with technological change and global interconnectedness. Competitive blacksmiths, for example, might come to regard the Internet as a valuable way of coupling their services to customers seeking decorative ironwork. Forging a path towards the successful development of high-tech drugs and low-tech ironwork both rely on effective positioning within an increasingly interconnected world. In both cases, knowing how to make a difference that meets evolving user expectations is the key to effective entrepreneurship; but further research is needed to explore the way in which the challenges differ. Whilst not appropriate for the UK pharmaceutical industry as described herein, Gibbons and co-workers' comments concerning the move towards Mode 2 working may well be key for those industries that are less reliant on basic research.

In adopting a knowledge perspective, this thesis has assumed that corporate R&D can be adequately explained as a form of knowledge working. In research, new knowledge is sought and created by experimentation to yield prototype products or processes. In development, existing knowledge is applied to adapt these prototype products or processes to meet the needs of the organization. But corporate R&D is more than knowledge working. It is about believing that the impossible can be made possible, that the problem can be solved. It is about the persistence to see a project through to completion. It is about championing as well as entrepreneuring (Roberts and Fusfeld, 1981, p.22) in order that new products or processes are accepted. It is about the use of imagination (Hurst *et al*, 1989, p.89) to explore and arrive at a new reality to which the hidden clues are pointing (Polanyi, 1966, p.24). It is above all a quest for the 'truth', albeit a scientific or technological 'truth' (Russell, 1931, p.103). As a consequence, the management of research and development is about envisioning the future, about inspiring the hearts and minds of the people who are engaged in the pursuit of that future, about intuition and experimentation to test the feasibility of that future, about observation and understanding to direct or redirect the results of further research or development, about encouragement when experiments fail, about flexibility of outcomes, and about flexibility in processes to achieve those outcomes. The management of both research and development is thus in conflict with 'traditional management' in a number of ways. In particular:

- Persistence to completion is not always economically viable for the company.
- Failure is part of experimentation, but is not to be encouraged in business.
- Company outcomes are normally pre-ordained, but the outcomes of research and development are not necessarily so.
- The quest for scientific 'truth' is not the prime directive, although it could lead to new opportunities.

In general, the findings of this study would, additionally, suggest that the 'more successful' pharmaceutical, biopharmaceutical and biotechnology companies reported upon herein do appear to have achieved a successful compromise between these conflicting requirements. They do seem to be able to channel the natural persistence of their research and development workers into the directions most appropriate for the company. They do try to learn from the failures that inevitably occur. Within the remit of their corporate objectives, they do work with their research and development staff to develop, wherever possible, the unexpected outcomes of experimentation. And, by collaborating and networking with others, they do keep abreast of the latest scientific and commercial 'truths' that may affect their activities. Above all, they do appear to encourage an environment of cooperation and facilitation throughout the organization and the extended organization and throughout the industry as a whole. As Alan McKinlay reports, 'It's all about going beyond teams – way beyond teams – it's all about creating communities' (McKinlay, 2000, p.114)

Finally, the focus of this thesis has been on the activities associated with the corporate R&D functions of organizations operating in the United Kingdom. However, knowledge-based approaches to competitive innovation might be developed in other institutional settings. Better understanding the process of knowing how to 'do things' – associated with creativity and the power to 'make a difference' – is important to making sense of practice, in any context. Moreover, comparisons between practices that are enabled and constrained in different institutional contexts promise new insights into the interaction between organizations and their operating environments.

References

Abernathy, W. J., and Clark, K. B. (1985) Innovation: Mapping the winds of creative destruction, *Research Policy*, Vol.14, pp.3-22.

Ahmed, P. K. (1998) Benchmarking innovation best practice, *Benchmarking for Quality Management & Technology*, Vol.5, No.1, pp.45-58.

Allen, T. J. (1977) *Managing the Flow of Technology: Technology Transfer and the Dissemination of Technological Information within the R&D Organization,* The MIT Press, Cambridge, Mass., USA.

Armbrecht Jr, F. M. R., Chapas, R. B., Chappelow, C. C., Farris, G. F., Friga, P. N., Hartz, C. A., McIlvaine, M. E., Postle, S. R., and Whitwell, G. E. (2001) Knowledge Management in Research and Development, *Research Technology Management*, Vol.44, No.4, pp.28-48.

Astley, W. G. (1978) Sources of Power in Organizational Life, *Unpublished PhD Dissertation,* University of Washington, Seattle, USA.

AstraZeneca (2000) *Annual Report and Form 20-F 2000.*

Bacon, F. (1906) *The World's Classics: The Advancement of Learning* and *New Atlantis*, reprinted 1966, Oxford University Press, London, UK.

Becerra-Fernandez, I., and Sabherwal, R. (2001) Organization Knowledge Management: A Contingency Perspective, *Journal of Management Information Systems*, Vol.18, No.1, pp.23-55.

Beeby, M., and Booth, C. (2000) Networks and inter-organizational learning: a critical review, *The Learning Organization*, Vol.7, No.2, pp.75-88.

Belbin, R. M. (1981) *Management Teams: Why they Succeed or Fail*, Butterworth-Heinemann, Oxford, UK.

Best, M. H. (1990) *The New Competition: Institutions of Industrial Restructuring,* Polity Press in association with Basil Blackwell, Cambridge, UK.

Boghani, A., Onassis, I., Benabadji, A., and Bijl, C. (1999) Globalization of R&D, *International Journal of Technology Management*, Vol.17, No.6, pp.696-710.

Bowonder, B., and Miyake, T. (1999) Japanese LCD industry: Competing through Knowledge Management, *Creativity and Innovation Management (UK)*, Vol.8, No.2, pp.77-99.

Brook, R. J. (1973) *Berkeley's Philosophy of Science,* International Archives of the History of Ideas, © 1973 by Martinus Nijhoff, The Hague, Netherlands.

Brown, J. S., and Duguid, P. (1998) Organizing Knowledge, *California Management Review*, Vol.40, No.3, Spring, pp.90-111.

Burns, T., and Stalker, C. M. (1961) *The Management of Innovation*, Tavistock Publications, London.

Burton, R. M., Forsyth, J. D., and Melick, D. M. (1988) Searching for viability under changing environmental conditions, *Technovation*, Vol.8, Chapter 7, pp.111-131.

Chemistry in Britain (2001) HLS finds friends in high places, *Chemistry in Britain*, March, pp.5-6.

Chemistry in Britain (2003) HLS wins injunction against Shac, *Chemistry in Britain*, June, p.5.

Chiesa, V. (1996) Evolutionary patterns in international research and development, *Integrated Manufacturing Systems*, Vol.7, No.2, pp.5-15.

Chumer, M., Hull, R., and Pritchard, C (2000) Situating Discussions About 'Knowledge', Introduction in Pritchard, C., Hull, R., Chumer, M., and Willmott, H. (Eds.).

Managing Knowledge: Critical Investigations of Work and Learning, Macmillan Critical perspectives on Work and Organisations Series, Macmillan Press Ltd., Basingstoke, UK, pp.xv-xxx.

Cilliers, P. (2000) Knowledge, Complexity, and Understanding, *Emergence*, Vol.2, No.4, pp.7-13.

Coates, J. F. (2001) Knowledge Management is a Person-to-Person Enterprise, *Research Technology Management,* Vol.44, No.3, pp.9-13.

Coghlan, A. (2003) Island of Discovery, *New Scientist*, April 12, pp.54-57.

Coles, M. (1999) Knowing is succeeding, *Director*, March, pp.60-63.

Conway, S. (1995) Informal Boundary-spanning Communication in the Innovation Process: An Empirical Study, *Technology Analysis & Strategic Management,* Vol.7, No.3,pp.327-341.

Cook, S. D. N., and Brown, J. S. (1999) Bridging Epistemologies: The Generative Dance between Organizational Knowledge and Organizational Knowing, *Organization Science*, Vol.10, No.4, pp.381-400.

Cooper, R., and Kleinschmidt, E. J. (1987) New Products: What Separates Winners from Losers? *Journal of Product Innovation Management*, Vol.4, No.3, pp.169-184, in Ahmed, P. K., 1998, Benchmarking innovation best practice, *Benchmarking for Quality Management & Technology*, Vol.5, No.1, pp.45-58.

Coulson-Thomas, C. J. (1997) The future of the organization: selected management and development issues, *Industrial and Commercial Training*, Vol.29, No.7, pp.204-207.

Crane, D. (1969) Social Structure in a Group of Scientists: A Test of the "Invisible College" Hypothesis, *American Sociological Review,* Vol.34, No.3, pp.335-352.

Crane, D. (1972) *Invisible Colleges: Diffusion of Knowledge in Scientific Communities,* The University of Chicago Press, Chicago, USA.

Daft, R. L. (1995) Why I Recommend that Your Manuscript be Rejected and What You Can Do About It, Chapter 9 in *Publishing in the Organisational Sciences, Ed. 2,* Cummings, L. L., and Frost, P. J. (Eds.), SAGE Publications.

Davenport, T. H. (1997) Ten principles of knowledge management and four case studies, *Knowledge & Process Management*, Vol.4, No.3, pp.187-208.

Davenport, T. H., and Grover, V. (2001) Special Issue: Knowledge Management, *Journal of Management Information Systems*, Vol.18, No.1, pp.3-4.

Davenport, T. H., and Prusak, L. (1998) *Working Knowledge: How Organizations Manage What They Know*, Harvard Business School Press, Boston, Mass., USA.

Davidson, J. M., Clamen, A., and Karol, R. A. (1999) Learning from the Best New Product Developers, *Research Technology Management*, Vol.42, No.4, pp.12-18.

Debackere, K., Clarysse, B., Wijnberg, N. M., and Rappa, M. A. (1994) Science and Industry: A Theory of Networks and Paradigms, *Technology Analysis & Strategic Management,* Vol.6, No.1, pp.21-37.

de Solla Price, D. (1975) *Science Since Babylon*, Yale University Press, New Haven, Connecticut, USA.

Despres, C., and Chauvel, D. (1999) Knowledge management(s), *Journal of Knowledge Management*, Vol.3, No.2, 110-120.

Dickson, K. E., and Hadjimanolis, A. (1998) Innovation and networking amongst small manufacturing firms in Cyprus, *International Journal of Entrepreneurial Behaviour & Research*, Vol.4, No.1, pp.5-17.

Drucker, P. (1969) *The Age of Discontinuity: Guidelines to our Changing Society,* Heinemann, London, UK.

Drucker P. (1985) The Discipline of Innovation, *Harvard Business Review*, Vol.63, No.3, May-June, pp.67-72.

Echeverri-Carroll, E. L. (1999) Knowledge flows in innovation networks: a comparative analysis of Japanese and US high-technology firms, *Journal of Knowledge Management*, Vol.3, No.4, pp.296-303.

Ekvall, G. (1991) The organizational culture of idea-management: a creative climate for the management of ideas, Chapter 7 in *Managing Innovation*, Henry, J., and Walker, D. (Eds.), SAGE Publications, pp.73-79.

Eriksen, C. W., and Kuethe, J. L. (1956) Avoidance Conditioning of Verbal Behavior Without Awareness: A Paradigm of Repression, *Journal of Abnormal and Social Psychology,* Vol.53, pp.203-209.

Faulkner, W. (1994) Conceptualizing Knowledge Used in Innovation: A Second Look at the Science-Technology Distinction and Industrial Innovation, *Science, Technology & Human Values*, Vol.19, No.4, pp.425-458.

Freeman, C. (1992) *The Economics of Hope: Essays on Technical Change, Economic Growth and the Environment,* Pinter Publishers, London, UK.

Fuller, S. (2003) *Kuhn vs. Popper: The Struggle for the Soul of Science,* Revolutions in Science Series, Icon Books Ltd., Cambridge, UK.

Galanopoulos, A. G., and Bacon, E. (1969) *Atlantis: The truth behind the legend,* Thomas Nelson & Sons Ltd., London, UK.

Gassmann, O., and von Zedtwitz, M. (1999) New concepts and trends in international R&D organization, *Research Policy*, Vol.28, pp.231-250.

Gibbons, M. (2001) Governance and the New Production of Knowledge, Chapter 3 in *Science, Technology and Governance,* (Science, Technology and the International Political Economy Series), de la Mothe, J. (Ed.), Continuum, London, UK.

Gibbons, M. (2003) Competition Processes and the Management of Innovation, *Prometheus,* Vol.21, No.4, pp.449-465.

Gibbons, M., and Johnston, R. (1974) The roles of science in technological innovation, *Research Policy,* Vol.3, pp.220-242.

Gibbons, M., Limoges, C., Nowotny, H., Schwartzman, S., Scott, P., and Trow, M. (1994) *The New Production of Knowledge: The Dynamics of Science and Research in Contemporary Societies*, Sage Publications, Inc., London, UK.

Glaser, B. G., and Strauss, A. L. (1967) *The Discovery of Grounded Theory: Strategies for Qualitative Research,* Aldine Publishing Company, Chicago, USA.

Goldman, S. L., Nagel, R. N., and Preiss, K. (1994) *Agile Competitors and Virtual Organizations: Strategies for Enriching the Customer*, Van Nostrand Reinhold, New York, NY, USA, in Rogers, D. M. Amidon, 1996, The Challenge of Fifth Generation R&D, *Research Technology Management*, Vol.39, No.4.

Graham, M. B. W. (1985) Industrial Research in the Age of Big Science, *Research on Technological Innovation, Management and Policy*, Vol.2, pp.47-79, Rosenbloom, R. S. (Ed.). © 1985 by JAI Press Inc., Greenwich, Connecticut, USA.

Gupta, B., Iyer, L. S., and Aronson, J.E. (2000) Knowledge management: practices and challenges, *Industrial Management and Data Systems*, Vol.100, No.1, pp.17-21.

Hall, R. (1992) The Strategic Analysis of Intangible Resources, *Strategic Management Journal,* Vol.13, pp.135-144.

Harvey-Jones, J. (1994) *Managing to Survive: A Guide to Management Through the 1990s*, Mandarin, London, UK. First Edition published 1963.

Hansen, M.T., and von Oetinger, B. (2001) Introducing T-Shaped Managers: Knowledge Management's Next Generation, *Harvard Business Review*, Vol.79, No.3, pp.106-116.

Hayes, N., and Walsham, G. (2000) Safe Enclaves, Political Enclaves and Knowledge Working, Chapter 5 in Pritchard, C., Hull, R., Chumer, M., and Willmott, H. (Eds.), *Managing Knowledge: Critical Investigations of Work and Learning,* Macmillan Critical perspectives on Work and Organisations Series, Macmillan Press Ltd., Basingstoke, UK, pp.69-87.

Hayman, D. (2002) quoted in 'Access to HIV/Aids medicine', *Chemistry in Britain*, January, p.12.

Henderson, R. (1994) Managing Innovation in the Information Age, *Harvard Business Review*, Vol.72, No.1, Jan-Feb, pp.100-105.

Hobsbawm, E. J. (1968) *Industry and Empire: An Economic History of Britain since 1750,* corrected edition, 1969, Weidenfeld and Nicolson by arrangement with Penguin Books Ltd., London, UK.

Huber, G. P. (1999) Facilitating Project Team Learning and Contributions to Organizational Knowledge, *Creativity and Innovation Management*, Vol.8, No.2, pp.70-76.

Hull, R. (2000) Knowledge Management and the Conduct of Expert Labour, Chapter 4 in Pritchard, C., Hull, R., Chumer, M., and Willmott, H. (Eds.), *Managing Knowledge: Critical Investigations of Work and Learning,* Macmillan Critical perspectives on Work and Organisations Series, Macmillan Press Ltd., Basingstoke, UK, pp.49-68.

Hurst, D. K., Rush, J. C., and White, R. E. (1989) *Strategic Management Journal* (1989), Vol.10, pp.87-105.

Inkpen, A. C., and Dinur, A. (1998) Knowledge management processes and international joint ventures, *Organization Science*, Vol.9, No.4, pp.454-468.

Itami, H. (1992) Firm as an informational 'ba' (interactive field), in *Information and Internationalization*, Ijiri, Y. (Ed.), Carnegie-Mellon University Press, Pittsburg, USA, in Ray, T., and Little, S. (2001).

Jewkes, J., Sawers, D., and Stillerman, R. (1958) *The Sources of Invention,* Macmillan & Co., Ltd., London, UK.

Jordan, J., and Jones, P. (1997) Assessing your Company's Knowledge Management Style, *Long Range Planning*, Vol.30, No.3, pp.392-398.

Kanter, R. M. (1983) *The Change Masters: Innovation and Entrepreneurship in the American Corporation,* A Touchstone Book, 1984 Edition, Simon & Schuster, Inc., New York, USA.

Kanter, R. M., Kao, J., and Wiersema, F. (Eds.) (1997) *Innovation: Breakthrough Ideas at 3M, Du Pont, GE, Pfizer, and Rubbermaid*, © Woodworks, Inc., HarperBusiness, Harper Collins Publishers, Inc., New York, NY, USA.

Kerlinger, F. N. (1969) *Foundations of Behavioral Research: Educational and Psychological Enquiry*, Holt International Edition, Holt, Rinehart & Winston, Inc., New York, NY, USA.

Kodama, M. (1999) Strategic business applications and new virtual knowledge-based businesses through community-based information networks, *Information Management and Computer Security*, Vol.7, No.4, pp.186-199.

Kuemmerle, W. (1998) Optimal scale for research and development in foreign environments - an investigation into size and performance of research and development laboratories abroad, *Research Policy*, Vol.27, No.2, pp.111-126.

Kuhn, T. S. (1962) *The Structure of Scientific Revolutions,* Third Edition, 1996, The University of Chicago Press, Chicago, USA.

Kuhn, T. S. (1970a) Logic of Discovery or Psychology of Research?, in Lakatos, I., and Musgrave, A. (Eds.) *Criticisms and the Growth of Knowledge*, Proceedings of the International Colloquium in the Philosophy of Science, London, 1965, Vol.4, Cambridge University Press, London, pp.1-23..

Kuhn, T. S. (1970b) Reflections on my Critics, in Lakatos, I., and Musgrave, A. (Eds.) *Criticisms and the Growth of Knowledge*, Proceedings of the International Colloquium in the Philosophy of Science, London, 1965, Vol.4, Cambridge University Press, London, pp.231-278.

Kumpe, T., and Bolwijn, P. T. (1994) Toward the Innovative Firm - Challenge for R&D Management, *Research Technology Management*, Vol.37, No.1, pp.38-44.

Lakatos, I. (1970) Falsification and the Methodology of Scientific Research Programmes, in Lakatos, I., and Musgrave, A. (Eds.) *Criticisms and the Growth of Knowledge*, Proceedings of the International Colloquium in the Philosophy of Science, London, 1965, Vol.4, Cambridge University Press, London, pp.91-195.

Langrish, J., Gibbons, M., Evans, W. G., and Jevons, F. R. (1972) *Wealth from Knowledge: Studies of Innovation in Industry, The Macmillan Press Ltd, London, UK.*

Lee, H. D. P. (1965) *Plato: Timaeus*, Penguin Books Ltd., Harmondsworth, UK.

Leonard-Barton, D. (1992) The Factory as a Learning Laboratory, *Sloan Management Review;* Vol.34, No.1, Fall, pp.23-39.

Leonard-Barton, D. (1995) *Wellsprings of Knowledge: Building and Sustaining the Sources of Innovation*, Harvard Business School Press, Boston, Mass., USA.

Liyanage, S., Greenfield, P. F., and Don, R. (1999) Towards a fourth generation R&D management model - research networks in knowledge management, *International Journal of Technology Management*, Vol.18, No.3-4, pp.372-393.

Loftus, J. (2001) Drug hunters at work, *New Scientist*, December 22/29, p.88-89.

Lorenz, C. (1990) *The Design Dimension: The New Competitive Weapon for Product Strategy & Global Marketing*, 2nd Edition, Blackwell Publishers, Oxford, UK.

Madhavan, R., and Grover, R. (1998) From Embedded Knowledge to Embodied Knowledge: New Product Development as Knowledge Management, *Journal of Marketing*, Vol.62, October, pp.1-12.

Maidique, M. A., and Patch, P. (1978) *Corporate Strategy and Technological Policy*, reprinted as Chapter 4: Technology and Business Strategy, in *Readings in the Management of Innovation*, 2nd Edition, 1988, Tushman, M. L., and Moore, W. L. (Eds.), Harper Business, pp.236-248. © 1978 by the President and Fellows of Harvard College.

Mansfield, E. (1985) How Rapidly Does New Industrial Technology Leak Out?, *The Journal of Industrial Economics,* Vol.34, No.2, December, pp.217-223.

McAdam, R., and McCreedy, S. (1999) A critical review of knowledge management models, *The Learning Organization*, Vol.6, No.3, pp.91-100.

McCleary, R. A., and Lazarus, R. S. (1949) Autonomic Discrimination without Awareness: An Interim Report, *Journal of Personality,* Vol.18, pp.172-179.

McElroy, M. W. (2000) Integrating complexity theory, knowledge management and organizational learning, *Journal of Knowledge Management*, Vol.4, No.3, pp.195-203.

McInerney, C., and LeFevre, D. (2000) Knowledge Managers: History and Challenges, Chapter 1 in Pritchard, C., Hull, R., Chumer, M., and Willmott, H. (Eds.),

Managing Knowledge: Critical Investigations of Work and Learning, Macmillan Critical perspectives on Work and Organisations Series, Macmillan Press Ltd., Basingstoke, UK, pp.1-19.

McKinlay, A. (2000) The Bearable Lightness Of Control: Organisational Reflexivity and the Politics of Knowledge Management, Chapter 7 in Pritchard, C., Hull, R., Chumer, M., and Willmott, H. (Eds.), *Managing Knowledge: Critical Investigations of Work and Learning,* Macmillan Critical perspectives on Work and Organisations Series, Macmillan Press Ltd., Basingstoke, UK, pp.107-121.

Meyer-Krahmer, F., and Reger, G. (1999) New perspectives on the innovation strategies of multinational enterprises: lessons for technology policy in Europe, *Research Policy*, Vol.28, No.7, pp.751-776.

Miles, M. B., and Huberman, A. M. (1984) *Qualitative Data Analysis: A Sourcebook of New Methods*, SAGE Publications, California, USA.

Miller, W. L. (1995) A Broader Mission for R&D, *Research Technology Management*, Vol.38, No.6, pp.24-36.

Mintzberg, H. (1979) *The Structuring of Organizations*, Prentice-Hall International, Inc., Englewood Cliffs, NJ, USA.

Morita, A., Reingold, E. M., and Shimomura, M. (1986) *Made in Japan: Akio Morita and Sony*, Fontana Paperbacks Edition. © 1986 by E. P. Dutton, a Division of Penguin Books USA Inc.

Myers, S., and Marquis, D. (1969) *Successful Industrial Innovations: A Study of Factors Underlying Innovation in Selected Firms,* NSF 69-17, The National Science Foundation, Washington, D.C., USA.

Nelson, R. R., and Winter, S. G. (1982) *An Evolutionary Theory of Economic Change*, Belknap Press, Cambridge, Mass., USA.

Newell, S., Scarbrough, H., Swan, J., and Hislop, D. (2000) Intranets and Knowledge Management: De-centred Technologies and the Limits of Technological Discourse, Chapter 6 in Pritchard, C., Hull, R., Chumer, M., and Willmott, H. (Eds.), *Managing Knowledge: Critical Investigations of Work and Learning,* Macmillan Critical perspectives on Work and Organisations Series, Macmillan Press Ltd., Basingstoke, UK, pp.88-106.

Niosi, J. (1999) The Internationalization of Industrial R&D: From technology transfer to the learning organization, *Research Policy*, Vol.28, pp.107-117.

Nonaka, I. (1994) A Dynamic Theory of Organizational Knowledge Creation, *Organization Science*, Vol.5, No.1, February, pp.14-37.

Nonaka, I., and Takeuchi, H. (1995) *The Knowledge Creating Company: How Japanese Companies Create the Dynamics of Innovation*, Oxford University Press, New York, NY, USA.

Nowotny, H., Scott, P., and Gibbons, M. (2001) *Re-Thinking Science: Knowledge and the Public in an Age of Uncertainty,* Polity Press, Cambridge, UK.

Nowotny, H., Scott, P., and Gibbons, M. (2003) Introduction: 'Mode 2' Revisited: The New Production of Knowledge, *Minerva,* Vol.41, pp.179-194.

Oliver, A. L., and Liebeskind, J. P. (1997/1998) Three Levels of Networking for Sourcing Intellectual Capital in Biotechnology: Implications for Studying Interorganizational Networks, *International Studies of Management & Organization*, Vol.27, No.4, Winter, pp.76-103.

Parikh, M. (2001) Knowledge Management Framework for High-Tech Research and Development, *Engineering Management Journal*, Vol.13, No.3, pp.27-33.

Pearson, A. W. (1991) Managing innovation: an uncertainty reduction process, in *Managing Innovation*, Part 1, Section 1(2), Henry, J., and Walker, D. (Eds.), SAGE Publications, pp.18-27.

Peters, T. (1983) The Mythology of Innovation, or a Skunkwork's Tale, Part I, *The Stanford Magazine.* © 1983 Stanford Alumni Association.

Polanyi, M. (1958) *Personal Knowledge: Towards a Post-Critical Philosophy*, University of Chicago Press, Chicago, USA, Corrected Edition, 1962, reprinted in 2002 by Routledge, London, UK.

Polanyi, M. (1962) The Republic of Science: Its Political and Economic Theory, *Minerva,* Vol.1, No.1, pp.54-73.

Polanyi, M. (1966) *The Tacit Dimension,* reprinted 1983 by Peter Smith, Gloucester, Mass., USA, in arrangement with Doubleday & Company, Inc.

Polanyi, M. (1969) *Knowing and Being: Essays by Michael Polanyi,* Routledge, London, UK.

Polanyi, M., and Prosch, H. (1975) *Meaning*, The University of Chicago Press, Chicago, USA.

Popper, K. R. (1963) *Conjectures and Refutations: The Growth of Scientific Knowledge,* Routledge Classics, 2002, Routledge, London, UK.

Popper, K. R. (1970) Normal Science and its Dangers, in Lakatos, I., and Musgrave, A. (Eds.) *Criticisms and the Growth of Knowledge*, Proceedings of the International Colloquium in the Philosophy of Science, London, 1965, Vol.4, Cambridge University Press, London, pp.51-58.

Powell, W. W., Koput, K. W., and Smith-Doerr, L. (1996) Interorganizational Collaboration and the Locus of Innovation: Networks of Learning in Biotechnology, *Administrative Science Quarterly*, Vol.41, No.1, pp.116-145.

Pyka, A. (2000) Informal networking and industrial lifecycles, *Technovation*, Vol.20, No.1, January, pp.25-35.

Quinn, J. B. (1985) Innovation and Corporate Strategy: Managed Chaos, in *Technology in Society, Special Issue: Technology in the Modern Corporation: A Strategic Perspective*, Vol.7, No.2/3, pp.263-279.

Quinn, J. B. (1992) *Intelligent Enterprise: A Knowledge and Service Based Paradigm for Industry,* The Free Press, New York, USA.

Quintas, P., and Brauner, E. J. (1999) Managing Knowledge and Innovation, *B823 Managing Knowledge (Unit 9)*, The Open University Business School, Milton Keynes, UK.

Quintas, P., and Jones, G. (1999) An Introduction to Managing Knowledge, *B823 Managing Knowledge (Unit 1)*, The Open University Business School, Milton Keynes, UK.

Quintas, P., Lefrere, P., Carlisle, Y., and Thomson, A. (1999) Managing Knowledge in an Organizational Context, *B823 Managing Knowledge (Unit 4)*, The Open University Business School, Milton Keynes, UK.

Quintas, P., Lefrere, P., and Jones, G. (1997) Knowledge Management: a Strategic Agenda, *Long Range Planning*, Vol.30, p.385.

Rappa, M. A., and Debackere, K. (1992) Technological communities and the diffusion of knowledge, *R&D Management,* Vol.22, No.3, pp.209-220.

Rappuoli, R. (2002) Why we must pay more, *New Scientist*, August 31, p.25.

Ray, T. (1998) Collaborative Research in Japan and the West: A Case-study of Britain's response to MITI's Fifth Generation Computer Initiative, Chapter 9 in *Technology and Innovation in Japan*, Hemmert, M., and Oberländer, C. (Eds.), Routledge, London, UK, pp.151-169.

Ray, T. (2001) Collective Tacit Knowledge, Technological Innovation and the Calm of Constant Creation: Lessons from Japan? *Internal Open University Business School Paper*, Milton Keynes, UK, September.

Ray, T. (2005) Making Sense of Managing Knowledge, *Internal Open University Business School Paper*, Milton Keynes, UK, March.

Ray, T., Carter, C., and Clegg, S. (2002) Japan as counterfactual: collective tacit knowledge, learning and power, *Internal Open University Business School Paper*, Milton Keynes, UK, April.

Ray, T., and Little, S. (2001) Communication and Context: Collective Tacit Knowledge and Practice in Japan's Workplace *ba*, *Creativity and Innovation Management*, Vol.10, No.3, September, pp.154-164.

Ray, T., Little, S., and Lawrenson, D. (2000) Managing Anglo-Japanese knowledge creation, *Internal Open University Business School Paper,* Milton Keynes, UK.

Rickards, T., and Moger, S. (1999) Special Issue: Innovation through Knowledge Management, *Creativity & Innovation Management*, Vol.8, No.2, pp. 67-69.

Roberts, E. B. (2001) Benchmarking Global Strategic Management of Technology, *Research Technology Management*, Vol.44, Issue 2, pp.25-36.

Roberts, E. B., and Fusfeld, A. R. (1981) Staffing the Innovative Technology-Based Organization, *Sloan Management Review*, Spring, pp.19-34.

Rogers, D. M. Amidon. (1996) The Challenge of Fifth Generation R&D, *Research Technology Management*, Vol.39, No.4, pp.33-41.

Rothwell, R. (1992) Successful industrial innovation: critical factors for the 1990s, *R&D Management,* Vol.22, No.3, pp.221-239.

Rothwell, R., Freeman, C., Horlsey, V. T. P., Jervis, A. B., Robertson, A. B., and Townsend, J. (1974) SAPPHO updated – project SAPPHO phase II, *Research Policy,* Vol.3, 258-291.

Rothwell, R., and Zegveld, W. (1985) *Reindustrialization and Technology,* Longman Group Limited, Harlow, Essex, UK.

Roussel, P. A., Saad, K. N., and Erickson, T. J. (1991) *Third Generation R&D: Managing the Link to Corporate Strategy, Arthur D. Little, Inc.*, Harvard Business School Press, Boston, Mass., USA.

Ruggles, R. L. (1997) *Knowledge Management Tools: Resources for the Knowledge-Based Economy*, Butterworth Heinemann, Boston, Mass., USA.

Ruggles, R. L. (1998) The State of the Notion: Knowledge Management in Practice, *California Management Review*, Vol.40, No.3, pp.80-89.

Russell, B. (1931) *The Scientific Outlook,* George Allen & Unwin Ltd., London, UK.

Sapsford, R. (1999) *Survey Research*, SAGE Publications, London, UK.

Schumpeter, J. (1935) The Analysis of Economic Change, Chapter 1 in *Readings in Business Cycle Theory, Blakiston Series of Republished Articles on Economics,* Vol.II, The Blakiston Company, Philadelphia, USA, pp.1-19.

Scott, D. (1985) *Everyman Revived: The Common Sense of Michael Polanyi,* 1995 Edition, William B. Eerdmans Publishing Company, Grand Rapids, Mich., USA, and Cambridge, UK.

Sharp, J. (1997) Communities of practice: a review of the literature, http://www.rcinet.com/~sharpj/cop-lit.htm [accessed 7 June 1999], in Quintas, P., Lefrere, P., Carlisle, Y., and Thomson, A. (1999) Managing Knowledge in an Organizational Context, *B823 Managing Knowledge (Unit 4)*, The Open University Business School, Milton Keynes, UK.

Sheppard, N. (1999) Michael Polanyi and the Philosophy of Science: The Viewpoint of a Practising Scientist, *Polanyiana*, Vol.8, No.1-2, http://www.kfki.hu/chemonet/polanyi/; http://www.ch.bme.hu/chemonet/polanyi/

Simon, H. A. (1991) Bounded Rationality and Organizational Learning, *Organization Science*, Vol.2, No.1, February, pp.125-134.

Smart, A. U., McCosh, A. M., Barrar, P., and Lloyd, A. D. (1999) The Management of Knowledge during Design and Implementation of Process Technologies, *Creativity and Innovation Management*, Vol.8, No.2, pp.100-111.

Smith, J. (2000) From R&D to strategic knowledge management: transitions and challenges for national laboratories, *R&D Management*, Vol.30, No.4, pp. 305-311.

Sohn, J. H. D. (2004) Measuring KM's contribution to R&D at Samsung, *KM Review,* Vol.7, No.2, pp.6-7.

Spradley, J. P. (1979) *The Ethnographic Interview*, Holt, Rinehart and Winston, New York, NY, USA.

Stevenson, R. (2001) Comparisons are onerous, *Chemistry in Britain*, November, p.33.

Stewart, T. A. (1997) *Intellectual Capital: The New Wealth of Organizations*, Nicholas Brealey Publishing Limited, London, UK.

Stewart, T. A. (2002) *The Wealth of Knowledge: Intellectual Capital and the Twenty-First Century Organization,* Nicholas Brealey Publishing, London, UK. © Utopia Limited 2001, 2002.

Tang, H. K. (1998) An integrative model of innovation in organizations, *Technovation*, Vol.18, No.5, pp.297-309.

Teresko, J. (1999) Using R&D to Drive Growth: More firms discover innovation should be a business process as well as a research process, *Industry Week*, Vol.248, No.6, March 15, pp.22-30.

The Economist (1997) World Education League: Who's top? *The Economist*, March 29, pp.25-27.

The Economist (2001) Too testing for some: The rise in educational standards is faltering, *The Economist*, September 22, p.34.

The Economist (2003) Exotic pursuits: Drug firms are starting to tackle tropical diseases, *The Economist*, February 1, p.60.

The Economist (2003) Hard numbers: Maths and science have gone into a dangerous decline in Britain, *The Economist*, April 19, pp.25-26.

The Economist (2003) Big Pharma: The benefits of hypertension: Growing pressure on pharmaceutical firms is a force for good, *The Economist*, December 6, p.12.

Thomas, R. J. (1994) *What Machines Can't Do: Politics and Technology in the Industrial Enterprise,* University of California Press, Berkeley, California, USA.

Thomson, A., Evers, S., Hunt, J., and McCracken, R. (1999) Extra-Organizational Knowledge Processes, *B823: Managing Knowledge (Unit 5)*, The Open University Business School, Milton Keynes, UK.

Tsoukas, H. (1996) The firm as a distributed knowledge system: A constructionist approach, *Strategic Management Journal,* Vol.17, Winter Special Issue, pp.11-25.

Utterback, J. M. (1994) *Mastering the Dynamics of Innovation: How Companies Can Seize Opportunities in the Face of Technological Change,* Harvard Business School Press, Boston, Massachusetts, USA. © 1994 by the President and Fellows of Harvard College.

Varma, R. (1995) Restructuring Corporate R&D: From an Autonomous to a Linkage Model, *Technology Analysis & Strategic Management*, Vol.7, No.2, pp.231-247.

von Hippel, E. (1976) The dominant role of users in the scientific instrument innovation process, *Research Policy,* Vol.5, No.3, pp.212-239.

von Hippel, E. (1978) Successful Industrial Products from Customer Ideas: Presentation of a new customer-active paradigm with evidence and implications, *Journal of Marketing*, Vol.42, No.1, January, pp.39-49.

von Hippel, E. (1988) *The Sources of Innovation,* Oxford University Press, New York, USA.

von Hippel, E., Thomke, S., and Sonnack, M. (1999) Creating Breakthroughs at 3M, *Harvard Business Review*, Vol.77, No.5, pp.47-57.

Walker, D. (1994) Innovation. *B822: Creative Management (Block 3)*, The Open University Business School, Milton Keynes, UK.

Weick, K. E. (1979) Cognitive processes in organizations, *Research in Organizational Behaviour*, Vol.1, pp.41-74.

Winter, S. G. (1987) Knowledge and Competence as Strategic Assets, Chapter 8 in *The Competitive Challenge: Strategies for Industrial Innovation and Renewal,* Teece, D. J. (Ed.), Ballinger Publishing Company, Cambridge, Mass., USA.

Zirger, B. J., and Maidique, M. (1990) A model of new product development: an empirical test, *Management Science*, Vol.36, No.7, pp.867-883.

Secondary Sources

Sources used for searching the literature

Literature searches were conducted using the Open Universities' Voyager system. This allowed access to a number of databases. The following proved most useful and were accessed periodically throughout the course of the study:

ABI/INFORM Global (Bell & Howell ProQuest Direct) @ www.umi.com

Anbar (International Management Library) @ www.anbar.com

BIDS (Bath Information and Data Dervices) @ www.bids.ac.uk

EBSCO (Academic Search Elite / Business Source Premier) @ www.global.ebscohost.com

Emerald (MCB University Press) @ www.emerald-library.com

Sources used to support and confirm the empirical data

Company reports and accounts:

American Home Products Corporation, Annual Report 2000

Amersham plc, Annual Report 2000

Amersham plc, Interim Results 7 August 2001

Antisoma plc, Annual Report and Accounts 2000

AstraZeneca plc, Annual Report & Form 20-F 2000

Bioglan Pharma plc, Annual Report & Accounts to 31 January 2000

Celltech Group plc, Interim Report for 6 Months ended 30th June 2000

Eli Lilly and Company, Annual Report 2001

Eli Lilly and Company, 2001 Annual Meeting of Shareholders Proxy Statement

GlaxoSmithKline, Half-Year Review 2001

GlaxoSmithKline, Half-Year Report 2001

Glaxo Wellcome plc, Annual Report & Accounts and Form 20-F 1999

Nycomed Amersham plc, Annual Report and Accounts 1999

Oxford BioMedica plc, Report & Accounts 2000

Oxford BioMedica plc, May 2000 Presentation

Pfizer Inc., 2000 Annual Report

SmithKline Beecham plc, Annual Report and Form 20-F 1999

Company websites

The following websites were accessed at approximately three monthly intervals throughout the period January 2001 and December 2003.

www.ahp.com

www.amersham.co.uk

www.amersham.com

www.amershambiosciences.com

www.amershamhealth.com

www.antisoma.com

www.apbiotech.com

www.astex-technology.com

www.astrazeneca.com

www.bioglan.com

www.charnwood.astrazeneca.com

www.elililly.com

www.gsk.com

www.lilly.co.uk

www.medeva.co.uk

www.oxfordbiomedica.co.uk

www.pfizer.com

www.sb.com

www.whitehall-robins.com

www.wsj.com

www.wyeth.com

General company and business information

Drug Discovery Technology: Europe 2001, Where Science meets Business, 23-26 April 2001, Messe Stuttgart International, Stuttgart, Germany, @ www.drugdisc.com – accessed 14 June 2001

The Economist: A Survey of the Pharmaceutical Industry, 21 February 1998

The Economist, Economist Newspaper Ltd, London, UK – between January 2000 and December 2002

Euromonitor: Global Market Information Database, World strategies: Global pharmaceutical manufacturers, December 2000, @ www.euromonitor.com – accessed 16 January 2002

Harvard Business Review, Harvard Business School Publication Corp., Watertown, Massachusetts, USA – between January 2000 and December 2002

Pharmaceutical Pricing and Reimbursement in Europe: Scrip Reports, @ www.pjbpubs.co.uk – accessed 14 June 2001

Sources used in determining corporate R&D success

Bureau van Dijk (FAME) company directory @ http://fame2.bvdep.com – between January 2000 and February 2002

Euromonitor: Global Market Information Database, @ www.euromonitor.com – between January 2000 and February 2002

Nature, Nature Publishing Group, Macmillan Publishing Ltd., London, UK – between January 2000 and June 2001

New Scientist, Reed Business Information Ltd., London, UK – between January 2000 and June 2001

Reed Information Services @ www.kompass.com – between January 2000 and February 2002

The Value Added Scoreboard 2000, DTI Publications, @ www.innovation.gov.uk

Appendix 4.1: Specimen Interview Request Letter

The Open University Business School
Walton Hall, Milton Keynes, MK7 6AA

24th July, 2001

To the R&D Director/ Manager
Company A
Address B

Dear Sir/ Madam,

Managing R&D

I wonder if you can help me. I am a 2nd year full-time PhD student with The Open University Business School researching the management of R&D. I am interested in the pharmaceutical and biotechnology industries because they are industries that seem to be doing something right in R&D, and could perhaps offer some 'best practice' guidelines for other UK industries. I have been able to obtain some information from your company's Annual Report and website, but I have specific questions regarding R&D approaches, R&D practices, and knowledge working in R&D that I would like answered. I would therefore very much appreciate it if the appropriate person within your organisation could spare me a little time to talk about these issues.

For information, I previously worked for 18 years as a chemist in the construction chemicals industry, and during that time completed a part-time MBA with The Open University. My interests now are concerned purely with the management of R&D. I would not need any specific information on your R&D projects, and any other information given me would of course be treated in confidence. I do not intend to undertake any 'case studies' as such, but would hope to use the information gained to look for general trends in R&D management. Specific information about your company need not be revealed, although your company would of course be acknowledged for its support.

Thank you for taking the time to read this letter.

Yours sincerely,

Christina R. Folkes, MBA
Direct Line: 01908 654660
Email: c.r.folkes@open.ac.uk

Appendix 4.2 The Interview Questions

SECTION A: Questions related to R&D Strategies and Structures

1. **Would you describe your work as mainly research (discovery), mainly development, mainly technical support, or a mixture of these?**

2. **Are your R&D operations carried out on an international basis?** Would you describe your R&D sites as 'Centres of Excellence'? Are they located close to external centres of excellence? To what extent is geographic proximity between R&D workers important in industrial R&D? To what extent have government regulations and initiatives influenced (a) the R&D location and/or (b) the type of work carried out? What do you think are the advantages/ disadvantages of R&D internationalisation to your company/ your R&D workers?

3. **Are your R&D sites autonomous, semi-autonomous, or totally integrated with each other?** How is the work of different R&D units controlled, steered, coordinated?

4. **To what extent has the type of work carried out affected the choice of R&D location?**

5. **To what extent has the location determined the type of work carried out?**

SECTION B: Questions related to Knowledge Processes in R&D

Knowledge Creation (the R&D process)

6. **How are projects initiated?** What are the drivers? Who are the influencers? Is it possible to relate the influencer with the type of R&D work undertaken? Has the 'Technology Foresight' programme influenced the R&D that your company now undertakes in the UK? Will such programmes influence the R&D that your company plans to undertake in the future?

7. **How are projects managed?** Are the research, development, technical support functions carried out separately or are they unified within a single department? Are projects an individual, team or networked affair? To what extent is R&D integrated with other departments? Is it possible to say to what extent external bodies - e.g. suppliers/ customers/ universities/ government bodies - are actively involved in the process?

8. **How are projects terminated?**

9. **Has the practice of R&D changed in recent years?**

Knowledge Application

10. **In your view, to what extent is existing knowledge a help or a hindrance in (a) adapting existing products or processes, (b) creating entirely new products or processes?**

11. **Do you have any processes within your company that assist R&D workers to learn from past events?** To what extent have these been successful in exploiting your company's existing knowledge?

Knowledge Acquisition

12. Accessing information from externally published sources is important in R&D? Do you have any support facilities for such processes?

13. **To what extent does your company acquire knowledge by in-licensing technology from external sources?**

14. To what extent is it important to your company that you develop your R&D workers internally as opposed to employing-in workers with knowledge in the field of interest?

15. **To what extent do you outsource your R&D work to others?** With whom would this work normally be outsourced?

16. Do you have any other ways of acquiring knowledge?

Knowledge Exploitation

17. **How important is technology out-licensing as opposed to in-house exploitation of your own intellectual property?**

Knowledge Sharing – Knowledge Networking

18. **Informal (non-company promoted) R&D networks have received some attention in the literature. What do you believe is the extent of such informal knowledge networking within your industry?** To what extent is such informal knowledge networking recognised and/or accepted by your company?

19. **Is it possible to say to what extent informal R&D networks (a) influence and/or (b) support the R&D work that your company undertakes?** In general, do existing knowledge networks determine the type of R&D undertaken, or are they the result of the way that R&D is practiced?

SECTION B: Questions related to Knowledge Processes in R&D – *Continued*

Knowledge Sharing – Knowledge Networking – *Continued*

20. **To what extent does your company promote/encourage knowledge networking (a) between R&D workers, both internally and externally, and/or (b) throughout the company as a whole? Have company promoted networking initiatives changed the practice of R&D in any way?**

21. **Has your company been involved in any Government initiatives to encourage external networking in R&D** (e.g. cross-industry visits)? Which companies were involved? To what extent have these initiatives benefited your own R&D activities? How important do you believe such initiatives will be to your company/ your R&D workers in the future?

22. **To what extent has your company embraced the 'electronic age'?** Do your R&D workers have access to email, company databases, computer conferencing, telephone conferencing, video conferencing, The Internet, etc? **To what extent have the new communication technologies changed (a) the networking activities of R&D personnel, (b) the management/ practice of R&D?**

Knowledge Sharing – Collaborative Ventures

23. **To what extent are collaborative research ventures important to your company?** With whom would you normally collaborate? Are these collaborations mainly formal (ie agreed by contract) or informal in nature? Do you have any informal arrangements with other parties? Has your company been involved in any Government promoted joint research collaborations? Did these initiatives bring benefits to your own R&D activities? How important do you believe such initiatives will be to your company and your R&D workers in the future? Have you ever collaborated / would you ever collaborate with a competitor?

24. **What advantages/ disadvantages have you found with such collaborative approaches?**

25. **In your experience, does one collaborative venture lead to another?**

SECTION C: A Final Question related to R&D in General

26. **What do you believe is the single most important factor to be considered in the successful management of industrial R&D?**

Appendix 5.1: The Companies

PHARMACEUTICAL COMPANIES (R&D Headquarters)	**BIOPHARMACEUTICAL COMPANIES**	**BIOTECHNOLOGY COMPANIES**
AHP (USA), AstraZeneca (Sweden/UK), Bioglan Pharma (UK), Eli Lilly (USA), GSK (UK), Pfizer (USA)	Antisoma Research Ltd (UK), Celltech Group plc (UK)	Amersham (UK), Astex Technology (UK), Oxford BioMedica (UK)
Large mature global and multinational companies with a UK, US, or Anglo-Swedish parent. All have R&D sites in the USA, UK and elsewhere. Most have an R&D presence in Japan. Recent trend to locate R&D headquarters outside of the UK, particularly to the USA.	One young semi-virtual organisation (Company-G) is based in the UK and has a single R&D site located within an external 'centre of excellence'. One multinational organisation (Company-H) is about 20 years old and is now one of the largest biopharmaceutical companies in Europe. It has several R&D sites in the UK (drug discovery) and the USA (gene discovery).	With one exception (Company-J) these companies are small (less than 50 people), young (less than 7 years old) and UK based. They were often started as spin-outs from academic research institutes and rely on venture capital or grants to provide funds for research. Company-J is a medium-sized company over 30 years old with R&D sites in Europe, North America, Japan and China.
Annual sales range from £ 60.5 million to £ 20 billion.	Annual sales range from £ 1.5 million to £ 114.5 million.	Annual sales range from zero to £ 1.4 million
Annual R&D investments range from £ 5.7 million to £3 billion and are typically 15-17% of sales.	Annual R&D investments range from £ 6.5 million to more than £ 50 million.	Annual R&D investments range from less than £ 0.9 million to £ 149 million.

Appendix 5.1: The Companies – *Continued*

PHARMACEUTICAL COMPANIES	BIOPHARMACEUTICAL COMPANIES	BIOTECHNOLOGY COMPANIES
R&D employees number from 251 to more than 16,000	R&D employees range from about 30 (Company-G) to 600 (Company-H).	Smaller companies typically employ less than 50 R&D workers, who constitute the majority of the workforce. Company-J has about 4,500 staff in production and development.
Most companies can carry out all operations from research (discovery) through to development, manufacture, marketing and sale of product. Two companies concentrate on prescription only drugs (Company-B and Company-F), three deal with both prescription and over-the-counter drugs (Company-A, Company-D, and Company-E), and one is involved with drug formulation and delivery systems (Company-C).	Company-G: Expertise is in managing the drug development process. The company in-licenses candidate therapies, outsources non-core tasks, and out-licenses product for other companies to manufacture, market and sell. In-house R&D is development orientated. Company-H: Both research and development is undertaken. It has a portfolio of marketed drugs and its own sales division. Manufacturing is outsourced.	R&D is research orientated. All companies are world leaders in a particular technology or technologies of use in medical diagnosis, treatment or research. All work extensively with pharmaceutical companies to develop these technologies further. They may offer contract services to others. They may undertake in-house drug discovery to 'proof of concept' stage.

PHARMACEUTICAL COMPANIES	BIOPHARMACEUTICAL COMPANIES	BIOTECHNOLOGY COMPANIES
Qu.1: **Would you describe your work as mainly research (discovery), mainly development, mainly technical support, or a mixture of these?**		
All companies carry out both research (discovery) and development. The larger companies have separate in-house technical support units. Additional uses for existing products can offer significant cost savings on the regulatory side and all pharmaceutical companies pursue such activities extensively, but there is still an emphasis on the discovery of new drugs. Increasingly, biotechnology is playing a major part in discovery, and it is not unheard of for pharmaceutical companies to acquire whole companies owning technology of strategic importance. Such technology is however usually available to all pharmaceutical companies under licence.	Company-G carries out development rather than research (although the company originally researched novel ways to target tumours using antibodies and small proteins). Company-H carries out research and development. It undertakes clinical trials, process R&D, formulation development, and internal manufacture.	Innovative research, product development and technical support. Company-I is perhaps more research orientated. Company-J also gives important consideration to product life-cycle management. But the importance of research – to stay at the forefront of new advances – is without question for all three companies.

PHARMACEUTICAL COMPANIES	BIOPHARMACEUTICAL COMPANIES	BIOTECHNOLOGY COMPANIES
Qu.2: **Are your R&D operations carried out on an international basis?** Would you describe your R&D sites as 'Centres of Excellence'? Is/are your research units located close to external centres of excellence? What do you think are the advantages/disadvantages of internationalisation in R&D to your company / to your R&D workers?		
All have internationalised their R&D operations. R&D headquarters are located in the USA, UK or Sweden. Research sites are 'centres of excellence' in that they tend to concentrate on a particular therapeutic area. Development sites are more general and would not normally be termed 'centres of excellence' although they will contain some excellent working. More recently established research sites are sited close to external centres of excellence, particularly in the USA. External centres of excellence may actually become a part of the organisation (Company-B). Older sites are located near manufacturing sites, which in turn are located close to river estuaries, where traditionally waste and effluent regulations were traditionally less severe (Company-A-1).	Company-G's development is UK based. Company-H has R&D sites in the UK and USA. R&D sites may be thought of as 'centres of excellence' in that they concentrate on activities for which the companies have world-class reputations. Company-G's in-house development is based within a centre of excellence. The main advantage of the location is that it allows access to the animal house facilities, the library and the equipment of a medical school. Two of Company-H's sites (both the results of acquisitions) are located close to external centres of excellence, although this is not seen as a future necessity.	Company-I's and Company-J's R&D operations have been internationalised. Company sites are mostly the 'centres of excellence' in their particular field of activity. R&D units of the smaller companies are often close to the external centres of excellence from which they originated. The larger company's R&D sites are fairly close to centres of excellence More than one interviewee felt that being located close to an external centre of excellence was not a future necessity since in most cases the companies are themselves the leaders in their fields.

PHARMACEUTICAL COMPANIES	BIOPHARMACEUTICAL COMPANIES	BIOTECHNOLOGY COMPANIES
Qu.2: **Are your R&D operations carried out on an international basis?** – *Continued*		
Internationalisation has enabled much greater use of global knowledge and expertise (Company-B). It has brought diversity and a full range of talent in research (Company-E).	Company-H acquired an overseas centre of excellence in gene technology in order to exploit the gene-to-drug pathway. Knowledge acquisition was the advantage sought in 'R&D internationalisation'.	Although not yet applicable to the majority of these companies, general reasons suggested include: easier access to (overseas) expertise in particular fields of technology, and a greater diversity in thinking. Disadvantages include the loss of a 'family' atmosphere and approach.
Qu.3: **Are your R&D sites autonomous, semi-autonomous, or totally integrated with each other?**		
Research sites are generally semi-autonomous: they have responsibility for a particular therapeutic / disease area but are required to meet global targets. Development units usually cover wider therapeutic areas. R&D strategies have a global perspective but there are local needs associated with the development of the final product (there is no universal procedure for gaining regulatory approval).	Sites are single units (Company-G) or semi-autonomous sites (Company-H) in that they have autonomy in their own specialties but they also share resources between sites and work together across science as well. R&D strategies take a global perspective. They are top-down, but with scope for bottom-up influence.	Sites are autonomous single units (Company-K) or semi-autonomous sites, having autonomy within a particular field of technology or therapeutic area (Company-I, Company-J). R&D strategies take a global perspective. They are usually determined by the executive board perhaps aided by a science advisory board.

PHARMACEUTICAL COMPANIES	BIOPHARMACEUTICAL COMPANIES	BIOTECHNOLOGY COMPANIES
Qu.3: **Are your R&D sites autonomous, semi-autonomous, or totally integrated with each other?** – *Continued*		
	Company-G's current strategy of in-licensing novel product candidates for pre-clinical and clinical development was questioned. The strategy allows the company to add shareholder value faster and at lower risk than if it conducted 'blue sky' research itself, but it is now easier for researchers themselves to obtain funds. The intermediate step offered by Company-G is unlikely to be needed in the future.	The eventual aim may be full in-house drug development leading to reclassification as a biopharmaceutical company. Company-J is perhaps some way along that route.
Qu.4: **To what extent has the type of work carried out affected the choice of R&D location?**		
By default and by acquisition, the type of work carried out has generally determined the choice of research location. (Company-A-1)	Company-H has grown by merger and acquisition, and the R&D sites just happen to be where the previous organisations were. Different sites do tend to concentrate on particular activities, but this was not thought to be a necessity in the future.	To a significant extent, yes. Spin-outs have tended to stay close to their original source of inception. Again, this was not felt to be a necessity in the future.
Qu.5: **To what extent has the location determined the type of work carried out?**		
Companies do emphasise the use of local R&D knowledge and expertise, so in this respect the location can determine the type of work carried out.	The closeness of Company-H's Seattle site to an external centre of excellence in genomics has tended to influence the type of work carried out at that location, but generally the location has little effect on the type of work carried out.	The expertise at the location has determined the type of work carried out at that location.

PHARMACEUTICAL COMPANIES	BIOPHARMACEUTICAL COMPANIES	BIOTECHNOLOGY COMPANIES
Qu.6: **How are projects initiated?** What are the drivers? Who are the influencers? Can the influencer be related to the type of work undertaken? Has the 'Technology Foresight' programme influenced the R&D that your company now undertakes in the UK? Will such programmes influence the R&D that your company plans to undertake in the future?		
Projects can come from anywhere. Likely current drivers are biological innovations. Universities, sister companies, patients and GPs, and The World Health Organization can be important influencers. Government is a regulating influence, although to some extent it may also influence the areas people work in. The companies have separate departments looking into in-licensing and out-licensing opportunities. Project initiation in research is to a lesser (Company-A, Company-B) and greater (Company-C, Company-D, Company-E-1, Company-F) extent dependent upon fit with corporate strategy. Projects can be thought of as (a) science/technology push (Company-A, Company-B), (b) market pull (Company-D, Company-E-1, Company-F), or (c) cross-functional coupling (Company-C).	In theory, anyone can raise a project idea. Partner companies and to a lesser extent universities, research institutes, and (in the case of Company-H) sister companies can influence which projects are undertaken. Both companies have departments that trawl the research world for in-licensing opportunities. Company-G: ideas are evaluated by the business development team and the board. Company-H: ideas are discussed at regular team meetings and decisions for project continuation are made by the research management team, the development management team, and the group development management team. Ideas should fit with the company's disease areas of interest.	Ideas can come from anywhere. Influencers may include customers, universities, and, rarely, suppliers. Governments are a regulating influence. Project initiation is dependent upon technical and commercial fit and, for Company-J, return on investment criteria. The commercial fit may be that of a partnering pharmaceutical or biotechnology company that is providing the finance and possibly some of the human resources for the work involved.

PHARMACEUTICAL COMPANIES	BIOPHARMACEUTICAL COMPANIES	BIOTECHNOLOGY COMPANIES
Qu.6: **How are projects initiated?** – *Continued*		
In the UK, Company-A and Company-B (science/technology push, and ideas from anywhere with fewer restrictions on selection) are perhaps better known for more innovative products than Company-C, Company-D, Company-E-1, and Company-F. There are people within the company who are actively involved in looking at what is coming next, so that best use can be made of new science and technologies as they arise (Company-A-2) Government exerts a negative / controlling influence rather than a positive influence, e.g. the Home Office requiring and controlling animal experimentation, the Medicines Control Agency controlling registrations. Technology Foresight programmes have had little influence on the R&D work undertaken and are unlikely to do so in the future. (Company-A-1)	In-licensed products will mean development rather than research. Company-G felt that universities and research institutes may initiate novel developments and possibly some applied research. Company-H felt that universities rarely initiated novel developments in their field of activity. Government initiatives in general have had very little influence on the work undertaken. Foresight type programmes are unlikely to influence future work.	Biotechnology companies are using or adapting a technology to meet a medical need. Pharmaceutical partners will normally have their own areas of interest which will influence the actual work undertaken in partnership. 'Foresight programmes have had little influence on the R&D work undertaken. Biotechnology companies are at the cutting edge of the science involved and have been contributors to visions such as Foresight rather than recipients. What Foresight did do was to establish a new network that allowed people to talk to each other and understand where things were moving. But actually agreeing what was going to be important in the next 10 years? That was probably guaranteed to be wrong' (Company-I). Foresight programmes are unlikely to influence future work.

PHARMACEUTICAL COMPANIES	BIOPHARMACEUTICAL COMPANIES	BIOTECHNOLOGY COMPANIES
Qu.7: **How are projects managed?** Are the research, development, technical support functions carried out separately or are they unified within a single department? Are projects an individual, team or networked affair? To what extent is R&D integrated with other departments? Is it possible to say to what extent external bodies – e.g. suppliers / customers / universities / government - are actively involved in the process?		
Research is separated from development because of differences in ways of thinking, ways of working, and the increasing costs as projects progress. The process is essentially linear but with overlaps and feedback loops. Feasibility studies are the responsibility of research personnel, individually or in small teams. Once an approach is validated, a research project becomes a (matrix controlled) multidisciplinary and sometimes global team effort to reach 'proof of concept' stage. Development follows initial clinical trials and usually involves one or more multifunctional teams adopting a 'rugby scrum' approach to take product through further clinical trials, manufacturing, registration, regulatory approval, launch and life-cycle support activities.	Company-G undertakes mainly development. Company-H separates research from development because what is required from research is different from what is required from development. The management structures are also completely different Projects involve multidisciplinary (and in the case of Company-H) multi-site teams headed and run by Project Managers having the responsibility to take projects through to completion within the separate functions (R or D). Functional lines are secondary.	The majority of work undertaken has a research orientation. Projects are generally a multidisciplinary team approach with matrix control, although in very small companies (Company-K) research may initially be an individual approach. Company-J: Projects can be multi-site and international. Product Managers oversee the development and introduction of new and changed products. Senior scientists are responsible for leading, supervising and motivating the activities of less experienced scientists. Company-I: Collaborative projects with external partners also involve the business development function within the matrix.

PHARMACEUTICAL COMPANIES	BIOPHARMACEUTICAL COMPANIES	BIOTECHNOLOGY COMPANIES
Qu.7: **How are projects managed? - *Continued***		
Development projects are generally monitored and controlled by a research management steering committee composed of senior managers and/or directors typically taken from discovery, development, regulatory, manufacturing and commercial departments. Sites are supported either internally (Company-A, Company-B, Company-D, Company-E-1, Company-F) or externally (Company-C) by specialist technology units (e.g. Bioinformatics, High Throughput Screening, Structural Chemistry, Analysis, etc).	Projects(R or D) are reviewed at regular intervals by the relevant management teams for continued technical and commercial feasibility. Science Advisory Boards appear to play only a limited role in the decision-making processes of both companies.	Projects are reviewed regularly (by the team and/or higher management) for continued technical and commercial viability. Collaborative partners (pharmaceutical companies, universities and other research institutes, and increasingly other biotechnology companies) are often involved in the R&D process. Governments may provide grants and promote collaborative research with government institutes.
Qu.8: **How are projects terminated?**		
Generally through regular review by the team and/or Steering Committee. However, several companies noted the tendency not to terminate or to terminate only with reluctance.	Monthly project review meetings determine continuing viability and, where necessary, make the decision to terminate.	By regular review of project progress by the team and/or board. Termination decisions are ideally by consensus (Company-I) or are the prerogative of higher management, sometimes (but rarely) aided by a Science Advisory Board.

PHARMACEUTICAL COMPANIES	BIOPHARMACEUTICAL COMPANIES	BIOTECHNOLOGY COMPANIES
Qu.9: **Has the practice of R&D changed in recent years?**		
The process is much more disciplined, with more accountable given to the bottom line (Company-A, Company-B, Company-D). Previously a competitive autonomous set of R&D sites competing with each other rather than external competitors. Now a set of autonomous sites working in allocated areas but with some allowance made for taking discoveries to 'proof of concept' outside the site's normal area of activity and then passing them on to the relevant site within the company or elsewhere (Company-B).	Company-G is a fairly young company and processes have tended to be informal. As the number of projects increases the need for some formality and accountability was thought necessary. Company-H is currently reviewing its processes to take account of its recent growth and diversification.	Most companies are young and in-house R&D practices are fairly informal. Collaborations will to some extent need to accommodate the practices of their partners, particularly when these are large pharmaceutical companies. R&D practices are expected to become more formalised as the companies grow and further products are developed. Company-J probably now takes a more disciplined approach and more accountable approach than formerly. There is also an increased focus on life cycle management of existing products.

PHARMACEUTICAL COMPANIES	BIOPHARMACEUTICAL COMPANIES	BIOTECHNOLOGY COMPANIES
Qu.10a: **In your view, to what extent is existing knowledge a help / hindrance in (a) adapting existing products or processes?**		
Existing knowledge is very clearly a help in adapting existing products or processes, but the product redevelopment is likely to be an evolution rather than a revolution (Company-C).	'What we've learnt on that first product does support what we've done on subsequent ones' (Company-G). 'Existing knowledge is a help and is actually key' in adapting existing products or processes. 'I'm struggling to think of ways in which it could be a negative thing … I suppose, going back to the mergers, in the sense that it does mean re-educating people' (Company-H).	Not currently applicable as most companies are new and are developing entirely new products or processes.
Qu.10b: **In your view, to what extent is existing knowledge a help / hindrance in (b) creating entirely new products or processes?**		
Existing knowledge may be a problem when creating entirely new products, but the process of discovery requires the assessment of experiments that have been done before as well as those that are new. Bringing in new knowledge, e.g. in the form of external consultants or people working in other fields, can often add a new dimension / a new way of thinking that will result in a revolutionary new product.	'Existing knowledge can be a help in creating new products or processes, although that knowledge need not be held within the company. However, existing ways of working can blind one to new ways of working and sometimes to the detriment of the company. The people that really stole the march on others were the ones that bought-in the large scale automated screening and rational order of design [in drug discovery]' (Company-G).	'People will come to particular problems with their own baggage ... they will be experienced research scientists and will know what Fred Bloggs did in 1992 ... But they have a training that does make them challenge perceived assumptions … that does try to make them think sideways and be creative ... so in that respect existing knowledge is not necessarily a hindrance in developing entirely new products or processes' (Company-I).

PHARMACEUTICAL COMPANIES	BIOPHARMACEUTICAL COMPANIES	BIOTECHNOLOGY COMPANIES
Qu.10b: **To what extent is existing knowledge a help / hindrance in (b) creating entirely new products or processes?** – *Continued*		
Existing knowledge is not necessarily a hindrance in creating entirely new products and processes (Company-B).	'The business is all about creating new things… we're very used to going into a completely new study area, researching the area and getting to know the important leaders [as well as] working from scratch' (Company-H). Inference: existing knowledge is not necessarily a hindrance?	
Qu.11: **Do you have any processes within your company that assist R&D workers to learn from past events?** To what extent have these been successful in exploiting your company's existing knowledge?		
Typical processes include: ▪ End-of-project reviews ▪ Project post-mortems ▪ Major incident reports ▪ Case studies with lessons learnt ▪ Research update presentations ▪ Teams training subsequent teams (Company-A-1, Company-E-2) ▪ Knowledge Management forum (Company-A-2) ▪ Lessons learnt database ▪ Experts database ▪ Computer simulations	In the past, both companies relied on the fact that they were small, everybody knew what was going on, and knowledge was available when needed. There were no formal processes. Company-G recognises that all subsequent products are going through the same process that the lead product has already gone through, and that their regulatory and clinical people are further up the 'learning curve' than they were the first time round. Project post-mortems are being proposed – what went wrong, what went right, and what should be done next time?	Most companies are small and do not have formal systems for learning from past events. Also, events are essentially new and most learning is 'on-the-job'. There is a wide range of technical databases available that provide information on chemical and biological structures and the results of previous experiments. They can help R&D workers to avoid 'reinventing the wheel'.

PHARMACEUTICAL COMPANIES	BIOPHARMACEUTICAL COMPANIES	BIOTECHNOLOGY COMPANIES
Qu.11: **Do you have any processes within your company that assist R&D workers to learn from past events?** – *Continued*		
Training is often necessary for new recruits, since the latest techniques are not always learnt during academic training. There are various technical databases available that detail chemical and biological structures and the results of previous experiments. Company-A has a process that is designed to encourage the sharing of ideas, approaches, and knowledge in general between different sites, looking at what works well at each site, and telling the other sites what is being done - 'a sort of federation approach of sharing between sites with a common purpose.' Most admit that they could do better, and that information / knowledge sharing is a bit *ad hoc*, but end-of-project reviews and the old team training the new team can be helpful once people overcome their initial reservations about learning from others (said to be a particular problem in research where innovation and	Another proposal is the sharing of externally gained knowledge through after-conference reviews. One of the companies that had merged with Company-H had a knowledge manager. The merged company does not, but it is bringing in new processes to capture and use knowledge. Examples include databases on contract research organisations used previously, information on requirements and time scales of clinical trials, and on the requirements for regulatory approval, etc. Company-G thought that more use should be made of people's relevant experience gained elsewhere – a hint of 'Not invented here'? Company-H now has a much better idea of what has been done in the past, by whom, for what reasons, and at what costs, but states that more is being done.	

PHARMACEUTICAL COMPANIES	BIOPHARMACEUTICAL COMPANIES	BIOTECHNOLOGY COMPANIES
Qu.11: **Do you have any processes within your company that assist R&D workers to learn from past events?** – *Continued*		
creativity is expected, and early training emphasises individual questioning, experimentation and learning from outcomes, rather than learning from others). In one case (Company-F) the in-house training packages are now commercially available to external workers. In another case (Company-A) the package which involves an innovative way of modelling the development process obtained thousands of hits on the company intranet after originally being sent to 15 people for trial purposes only. Most admit that much of the 'knowledge' content is historical and may not necessarily apply in the future. Lessons databases suffer from access problems – how do you know what is relevant to you? Search criteria need to be carefully designed.		

PHARMACEUTICAL COMPANIES	BIOPHARMACEUTICAL COMPANIES	BIOTECHNOLOGY COMPANIES
Qu.12: Accessing information from externally published sources is important in R&D? Do you have any support facilities for such processes?		
Accessing information is part of due diligence feasibility. All, except Company-C, have library support services that have people trained in scientific search techniques to support R&D staff.	Company-G personnel have access to a medical school library and have support facilities for the acquisition of scientific papers. Company-H personnel have library and database support facilities.	Access to academic journals, commercial databases, patents, and the Internet are available, but most companies do not have support services for their R&D personnel. (Company-J is perhaps the exception.)
Qu.13: To what extent does your company acquire knowledge by in-licensing technology from external sources?		
Technology is in-licensed extensively, particularly from the newer biotechnology firms with the latest processes and methods of analysis. Drugs, vaccines, etc., are in-licensed from other pharmaceutical / biopharmaceutical companies to fill / augment product portfolios. There is an acceptance in all companies that one company cannot do everything.	All of Company-G's development projects are the result of in-licensing (drugs and technology) from cancer research and other academic and commercial institutions. In-licensing (and partnering) agreements have been particularly important in enabling Company-H to build its strengths in drug discovery and rapid product development.	In-licensing (Company-I) and strategic partnering (Company-J) is used fairly extensively to access new technology. Most companies are small and acknowledge that they cannot expect to do everything they need. Licensors/partners include major academic research centres, and biotechnology and pharmaceutical companies.
Qu.14: To what extent is it important to your company that you develop your R&D workers internally		
Extremely important - Discovery cannot survive without continual knowledge renewal. Expertise will be bought-in, particularly for new fields of activity, but workers are developed as well. (Company-B).	Being semi-virtual, most of Company-G's work is out-sourced. Nevertheless internal development of existing staff and recruitment of new staff is important as the company grows.	Intellectual property is recognised as a key asset and companies have a strong record in developing and continuing to develop state-of-the-art technologies and perhaps drug candidates, both internally and in collaboration with others.

PHARMACEUTICAL COMPANIES	BIOPHARMACEUTICAL COMPANIES	BIOTECHNOLOGY COMPANIES
Qu.14: To what extent is it important to your company that you develop your R&D workers internally – *Continued*		
Companies highly value and will vigorously defend their own intellectual property (patents). Product application extensions further develop existing personnel.	Company-H tries to build key expertise in-house. However, the amount of work varies from time to time and contract organisations are frequently and extensively used. These relationships can be long term, especially when the contractor has expertise in an area of particular interest.	As well as growing R&D staff technically, biotechnology companies have tended to grow their technical people into commercial and management roles.
Qu.15: **To what extent do you outsource your R&D work to others?** With whom would this work normally be outsourced?		
Many components may be outsourced (generally through the scientific lines), but whole projects are not.	Most of Company-G's work is development which is outsourced. The company manages the overall process. Discovery is all in-house within Company-H. Very occasionally a discovery has been outsourced to a larger pharmaceutical company for development.	Work is not outsourced.
Qu.16: Do you have any other ways of acquiring knowledge that haven't been mentioned so far?		
Companies employ information from wherever they can get it (the Internet, conferences, links with counterparts in other pharmaceutical companies. Knowledge can come from company mergers and acquisitions, product acquisitions, the Media, etc.	Company-H has acquired a significant amount of knowledge as the result of its various mergers and acquisitions.	Company acquisitions can considerably increase the R&D knowledge and skills bases. Combining new knowledge and skills can lead to further knowledge. In the case of Company-K, intellectual property agreements exist with the University of Cambridge relating to research undertaken by the founding scientists.

PHARMACEUTICAL COMPANIES	BIOPHARMACEUTICAL COMPANIES	BIOTECHNOLOGY COMPANIES
Qu.17: **How important is technology out-licensing as opposed to in-house exploitation of your own intellectual property?**		
Important. This is a major activity for all companies, and most have a central function looking into out-licensing (and in-licensing) opportunities from a global perspective. Out-licensing provides additional revenues for internal R&D. For smaller companies, out-licensing allows (easier) access to new geographic markets and provides revenue for growth. Companies generally out-license non-core products and technology. Cross-licensing of products in a particular therapeutic area between major pharmaceutical companies is quite common. Some believe that product out-licensing will become increasingly important (Company-A-3). Other, smaller companies (Company-C), who are already very dependent on out-licensing, believe that, over time, their dependency on out-licensing will be reduced.	Out-licensing is particularly important at the clinical trials stage. Companies do not have the financial resources to pay for the huge costs of final development. Neither do they usually have the marketing and sales forces needed for final product launch and sale. (This is changing for Company-H. 'By marketing selected products discovered in its research division through its newly acquired sales division Company-H hopes to retain a greater share of the gross profit than would be obtained through out-licensing.') Company-G could possibly exploit in-house and externally more of its own intellectual property – 'There are things that we have developed that could be useful to other people, but we don't seem to do it very much... We need to back-integrate ourselves much more into research. We certainly have the people who can do it.' Companies generally outsource product manufacture.	Out-licensing is particularly important. Most biotech companies do not have the financial or human resources to fully exploit their own technology in-house. Neither do they see this as part of their remit. They are consequently dependent upon pharmaceutical companies to license-in their technology for drug discovery and development. This is perhaps one reason why collaborations between biotechnology companies and pharmaceutical companies prevail – it is in the interests of both parties to develop the technologies as far as possible. Some drug discovery work may be undertaken in-house, usually as far as target identification or perhaps to 'proof of concept'. The resulting drug candidates are then out-licensed again to pharmaceutical companies.

PHARMACEUTICAL COMPANIES	BIOPHARMACEUTICAL COMPANIES	BIOTECHNOLOGY COMPANIES
Qu.18a: **Informal (non-company promoted) knowledge networks have received some attention in the literature. What do you believe is the extent of such informal networking within your industry?**		
'It is widespread and vital. People read the literature and go to conferences … We don't talk about the intimate details of what we do, but rather the technology and the processes that surround it' (Company-B). 'Generally in terms of the lines, the scientific disciplines, there is a lot of exchange of ideas, information, knowledge, as is traditional in the wider scientific community … it's not emphasis on the most sensitive stuff, but it's a culture of collaboration and sharing' (Company-A-1).	'To some extent scientists are differently motivated from other people… there goal in life isn't necessarily to promote the company's activities, it's more to be seen as important by their own peer group. So, going to conferences and getting publications and that kind of networking, they see that as their community rather than the company. So there's quite a lot of informal networking goes on' (Company-G). 'Within research it is huge. People go to international meetings, pharmacologists know each other, they chat, they move between jobs. So they get to know each other. It is an important way of sharing information. When it comes to development, people become more secretive … we wouldn't dream of giving each other anything that could be construed as proprietary information' (Company-H).	'Widespread. I'm sure a lot of that goes on ... at conferences, as the result of contact regarding publications, and particularly because of movement of people between companies, etc.' (Company-I).

PHARMACEUTICAL COMPANIES	BIOPHARMACEUTICAL COMPANIES	BIOTECHNOLOGY COMPANIES
Qu.18b: To what extent is such informal networking recognised by your company?		
Informal networking is widely recognised and generally supported. 'Scientists are scientists. They do talk to one another' (Company-F).	'Without question. There is obviously a tension between commercial needs for secrecy and the 'academic' world of conferences in which information is supposed to be freely available … so they [the scientists] have to tread a fine line… but because our founders have an academic background they are quite positive about that' (Company-G). 'I'm not sure that they do officially, but I don't think it would work if it didn't happen' (Company-H).	It is recognised as part of the knowledge sharing / knowledge acquisition needs of R&D and is generally supported. It is also recognised as a possible route to accessing the relevant commercial contact within companies (Company-I).
Qu.19a: **Is it possible to say to what extent informal R&D knowledge networks (a) influence the R&D work that your company undertakes?**		
Such networks are useful as a source of ideas that may well be novel to the company and to that extent they are important, but their degree of importance is difficult, if not impossible, to define. 'Someone might well come back from a conference, for instance, and say, 'I was talking to Jo Bloggs and we had this idea,' and it might lead to a project. So yes it can have an influence. How great it is I wouldn't like to guess' (Company-B).	A great deal. Meetings and conferences can be particularly useful for coming up with new ideas (Company-G).	'They can do and often it can be in ways that you don't appreciate at the time, but to what extent is difficult to say' (Company-I).

PHARMACEUTICAL COMPANIES	BIOPHARMACEUTICAL COMPANIES	BIOTECHNOLOGY COMPANIES
Qu.19b: **Is it possible to say to what extent informal R&D knowledge networks (b) support the R&D work that your company undertakes?**		
They can be very useful in gaining an understanding of what the regulatory authorities actually require for product licensing - e.g. where the short-cuts can be made, etc. They harmonise the industry views regarding regulatory issues, so avoiding attack by the inspectors - i.e. defensive power of the group rather than offensive power.	'They really are very important to help people progress and, particularly in research, people need to bounce ideas off each other, and because there are, maybe, only a couple of people in each company in any particular specialist area they almost need to get together' (Company-H).	They may be useful if you are having a problem with a standard laboratory process. You can talk [to your counterpart elsewhere] about the mechanics of it, without giving away too much detail (Company-I).
Qu.20a: **To what extent does your company promote / encourage networking (a) Between R&D workers, both internally and externally?**		
Most companies interviewed accept that scientists do need and want to share general technical information, and do encourage a 'knowledge sharing culture' both internally and externally. Attendance at external conferences is usually encouraged. It is not discouraged. Publishing findings and giving presentations on non-sensitive material is seen as one way of rewarding the scientist for the work done.	Internal and external networking is encouraged. Publishing papers (on less sensitive material) and giving presentations at seminars and conferences is also encouraged, and is seen as one way of rewarding research staff for work well done. Such activities can build the reputation of the researcher and in turn the reputation of the company (Company-G). R&D staff are encouraged to attend external meetings and then share their findings internally (Company-H).	Most companies expect their researchers to network internally and externally with partners. Most also encourage external networking in general. Conference presentations and publications of new scientific knowledge are part of the R&D process. Company-J has instigated an Internet based Imaging Research Network. However, as well as sharing knowledge between researchers, they perhaps also hope that it will promote their latest imaging technology!

PHARMACEUTICAL COMPANIES	BIOPHARMACEUTICAL COMPANIES	BIOTECHNOLOGY COMPANIES
Qu.20b: **To what extent does your company promote / encourage networking (b) throughout the company as a whole?**		
This is seen to be very important. Company intranets are common, but their usage is variable. Key business priorities are generally cascaded throughout the organisations to ensure a unified focus and purpose. Sharing the unique knowledge in discovery across the organisation means that all therapy areas are aware of the latest internal developments that may be of use to their teams. Personnel from discovery to launch are involved at some stage, to a greater or lesser extent, during development, to ensure knowledge continuity / revision as projects progress. The joint aim of bringing a product to market means that development teams work very closely with their marketing counterparts.	This is important, but is somewhat *ad hoc*. 'There's a shared drive where people lodge copies of their key files… The guys in the labs have got a nice little intranet that I would love to see extended … We are at that stage in our growth where we're getting too big for everyone to know everything … what we need to do now is get policies in place' (Company-G). Some sites have monthly site briefings; others have weekly presentations where different people are allotted to pass down information from the top. The Intranet is used quite a lot, and most groups have regular meetings for sharing information (Company-H).	Most Biotech companies are small (less than 80 people in total) and networking throughout the company is relatively easy. 'You're always bumping into each other … you know what's going on, so networking is dead easy' (Company-I). Company-J has more than 9000 employees (more than 1000 scientists), but nevertheless claims to consult with all staff on Group objectives, plans and progress, and on matters of general or particular interest through formal consultative arrangements at corporate and local level.
Qu.20c: **Have company promoted networking initiatives changed the practice of R&D in any way?**		
Not to any great extent. The R&D profile has perhaps been raised a little (Company-D, Company-E)?	No. There has always been a sharing culture.	Collaborative R&D and the networks built have probably led to R&D being less parochial (Company-I).

PHARMACEUTICAL COMPANIES	BIOPHARMACEUTICAL COMPANIES	BIOTECHNOLOGY COMPANIES
Qu.21: **Has your company been involved in any Government initiatives to encourage external networking in R&D?** Have these initiatives benefited your R&D activities? Will such initiatives be important in the future?		
Not to any great extent. A lot of the areas dealt with are very technical and perhaps don't have an equivalent where you can go out and learn from other industries... Similarly on the commercial side the industry in the UK is different / unique in that direct sales / advertising to the consumer is not allowed. Sharing Project Management techniques may perhaps be the exception to the rule whereby cross-industry networking might help all (Company-A-1).	As well as being members of various industry associations which have links to government, some of Company-G's staff are also members of 'London First', a government quango which promotes industry and infrastructure in the London area. There is currently a biotechnology initiative, Bio-Wednesday, which holds monthly talks on a technical subject followed by a cheese and wine supper and the chance to chat. By mixing CEOs, managers, academics, industrial scientists, intellectual property advisors, etc, it is hoped to encourage closer collaboration between industry and the London research hospitals to everyone's mutual benefit.	As far as was known, the companies had not been involved in any such initiatives.
Qu.22a: **To what extent has your company embraced the 'electronic age'?** Do your R&D workers have access to email, company databases, computer conferencing, video conferencing, the Internet, etc.?		
R&D personnel generally have access to all of the above mentioned technologies. Email, company intranets and databases, and the Internet are used extensively.	R&D personnel have access to the usual electronic systems. Email is used extensively. The Internet is a useful source of information.	Most of the above technologies are available to R&D staff. Email, the Internet, and telephone conferencing is particularly used.

PHARMACEUTICAL COMPANIES	BIOPHARMACEUTICAL COMPANIES	BIOTECHNOLOGY COMPANIES
Qu.22a: **To what extent has your company embraced the 'electronic age'?** – *Continued*		
Computer conferencing has been little used, telephone conferencing and, to a lesser extent, video conferencing being preferred. R&D personnel generally have access to modify relevant company databases. They also have access to a range of external technical databases and libraries to aid target identification and validation useful in drug discovery. Face-to-face meetings are still deemed important.	Conferencing systems have been little used in the past; although in the case of Company-H telephone conferencing is increasing as the number of R&D sites increases and the work (particularly in development) is carried out across sites. Company-H is also looking into electronic document handling. Face-to-face meetings are still deemed important. Both companies have grown in recent years and there is the feeling that a more strategic approach to IT is now needed.	Video conferencing is useful for sending documents and other items that need to be seen. There are a number of useful technical databases on the Internet. Electronic laboratory notebooks will be particularly useful once verifiable date entry is possible (a particular requirement for claiming patents in the USA).
Qu.22b: **To what extent have the new communication technologies changed the networking activities or the practice of R&D?**		
Email is time friendly and allows messages to be read / replied to at personal convenience and thus can assist networking activities.	Email is fast and time-friendly, and by replacing the fax machine has certainly aided external communications during clinical development trials.	Electronic searching is considerably faster than manual searching, and if it is done well can reduce development times.

PHARMACEUTICAL COMPANIES	BIOPHARMACEUTICAL COMPANIES	BIOTECHNOLOGY COMPANIES
Qu.22b: **To what extent have the new communication technologies changed networking activities or the practice of R&D?** – *Continued*		
Electronic searching has increased the rate at which information can be accessed (reducing development times) and increased the amount of information available (enabling companies to be more sure that what they intend to do hasn't been done before). The use of project management packages have given transparency to the R&D process, enabling others to appreciate more the successes and difficulties experienced, and enabling them to offer help as appropriate. Such tools also enable more effective scheduling of project tasks and of the projects themselves (Company-E).	There are a number of technical software packages that aid discovery and development (e.g. packages that compare compounds and their properties can reduce, but not entirely replace, laboratory time (Company-G). It is not thought to have altered networking patterns between R&D workers: people now email each other rather than talk to one another. It has probably increased networking throughout the company as a whole: managers and others are now copied into (relevant) emails between R&D staff. However, one of the problems in an industry where everything is documented and audited is that emails can be quite casual communications, and 'you can end up with a permanent record which isn't always appropriate' (Company-H).	

PHARMACEUTICAL COMPANIES	BIOPHARMACEUTICAL COMPANIES	BIOTECHNOLOGY COMPANIES
Qu.23a: **To what extent are collaborative research and development ventures important to your company?**		
Collaborations abound in development. They are important for both young and mature companies. They provide the necessary resources for younger companies with limited personnel, financial assets, and marketing and sales facilities. In mature companies they add to the gene pool of ideas and give access to the latest research and research techniques. 'It is one of the ways that you can use the genetic material that's out there in the widest sense [since] the number of people who you could employ is limited. They create knowledge that we wouldn't otherwise have' (Company-B).	Company-G has some collaborative 'research ventures despite being a 'development' company, and these are seen to be particularly important for the future of the company. The main reason for collaborative ventures is to gain expertise that is not available in-house. Company-H has a history of using contract research organisations for such purposes, and these collaborations can be of long standing.	These ventures are very important and extensive. They help companies to maximise their research and development expenditures: costs may be shared, or often the partnering company will pay for the technology development in return for some (limited) exclusivity to the final process or product. They also improve customer focus, and may improve the company's standing in the industry. They allow entry into drug development (albeit at the cost of sharing any ultimate rewards), the costs and risks of which would otherwise be prohibitive for a small, often financially stretched company.
Qu.23b: **With whom would you normally collaborate?**		
With biopharmaceutical / biotechnology companies to gain access to new research results / new technologies and, in return, provide the resources for the further development of promising products or technologies. With other pharmaceutical companies to research/develop new products.	With CRADAs – Collaborative Research and Development Agreements – in the USA. With academic institutes around the world for 'blue sky' research. With pharmaceutical companies to build strengths in drug discovery at minimal cost.	There are extensive research collaborations with leading pharmaceutical companies (who have the resources to help in the development of new and existing technologies and candidate drugs), and academic centres of excellence (to access and use the latest technical knowledge).

PHARMACEUTICAL COMPANIES	BIOPHARMACEUTICAL COMPANIES	BIOTECHNOLOGY COMPANIES
Qu.23b: **With whom would you normally collaborate?** – *Continued*		
With universities (for blue sky research that cannot be done in-house due to commercial pressures). With Regulatory authorities (to increase the understanding of the new product and ease the path to market). Note: Often new products require new analytical techniques to show their quality / efficacy / safety for use. This means <u>working with</u> the regulatory authorities to develop a process understandable by and acceptable to both parties. Without this, the product will not be approved. All such collaborations are likely to continue.		Collaborations with key individuals who can contribute expertise and intellectual property in therapeutic areas of interest have also been formed. Biotechnology companies will also combine their technologies to develop new ways of doing things.
Qu.23c: **Are these collaborations mainly formal (agreed by contract) or informal in nature?**		
Collaborations are nearly always formal (agreed by contract) since huge sums of money are involved in drug development (typically US $500 million +).	Collaborations are mainly formal in nature. 'Because of the issues with patents and technology know-how we have to be very formal and have everything documented… Having said that … it's important that we work as a team with the other company' (Company-H)	Most collaborations are formal (agreed by contract).

PHARMACEUTICAL COMPANIES	BIOPHARMACEUTICAL COMPANIES	BIOTECHNOLOGY COMPANIES
Qu.23d: **Do you have any informal arrangements with other parties, e.g. other companies, universities, research organisations?**		
Links are maintained with universities in particular to keep abreast of the latest developments. These can be informal in nature.	Companies maintain links with experts in the therapeutic fields of interest. 'They don't usually come and give us ideas for drugs .... But they will very much help us develop things at the early stage' (Company-H).	Many academics act as consultants, and although discussions can be informal in nature, they are nevertheless normally subject to some form of agreement to maintain confidentiality.
Qu.23e: **Has your company been involved in any Government promoted joint research collaborations?** Who were the major participants? Did these initiatives bring benefits to your own R&D activities? How important do you believe such initiatives will be to your company / your R&D workers in the future?		
Rarely. Several companies have been involved in some recent World Health Organization initiatives. Apart from a 'good press' and perhaps a general 'feel good' factor benefits are hard to define.	Nothing with the UK government. Companies have been involved with CRADAs, US Government promoted collaborations.	Rarely, if at all.
Qu.23f: **Have you ever collaborated / would you ever collaborate with a competitor?**		
Most have collaborated with competitors, either directly or as part of a university-led collaborative research project, but opinion is divided over whether such collaborations will continue. The problems associated with a lack of control over such projects (Company-B) needs to be weighed carefully against the possible knowledge gained (Company-A-3).	CRADAs may include collaborations with companies that could be seen as competitors.	Cross-licensing agreements are known (e.g. Company-J with SONUS Pharmaceuticals, for ultrasound technology).

PHARMACEUTICAL COMPANIES	BIOPHARMACEUTICAL COMPANIES	BIOTECHNOLOGY COMPANIES
Qu.24: **What advantages / disadvantages have you found with such collaborative approaches?**		
They provide relatively easy access to new technologies, resources for younger companies, and leverage the resources of older companies. They can produce novel products / technologies by combining the knowledge and expertise of the partners. Shared costs are reduced financial costs for each partner, but at the cost of increased complexity and lack of overall control of the process, and only shared ownership of the outcome.	They allow access to external resources and competencies at minimal financial cost. They reduce the risks and costs of clinical trials. They bring new ideas into the company. Cultural differences (large relatively inflexible firms versus small relatively flexible firms, hierarchical versus empowered firms) can lead to conflicts but these generally get solved. 'It's all a part of working together … but decision-making may be slower' (Company-H).	They maximise research expenditure. They increase in-house knowledge. They allow participation in the drug development process at minimal financial risk but with the resulting financial benefits. They can create market opportunities outside the company's normal field of activity.
Qu.25: **In your experience, does one collaborative venture lead to another?**		
Successful collaborations do lead to further joint working because the expectation is that the new collaboration will also be productive. This continues until the partner no longer has further knowledge to contribute (Company-B). Existing collaborations often suggest ideas for further work. The existing collaboration can either be extended or may lead to an entirely different piece of work (Company-C).	'Definitely, yes' (Company-H).	They can if previous ventures have been successful (Company-I).

Appendix 5.9: The Most Important Factors in Managing R&D

PHARMACEUTICAL COMPANIES	BIOPHARMACEUTICAL COMPANIES	BIOTECHNOLOGY COMPANIES
Qu.26: **What do you believe is the single most important factor to be considered in the successful management of R&D?**		
'A clear focus, with everyone knowing what you are trying to achieve, and with everyone knowing their part, their role in that. All the other things come to nothing if you're not all on the same side, if you're not all heading in the same direction. I just see the whole process as a team knowing what they're going to do, and they've all got the same colour shirt on and they know who's defending and who's attacking and so on' (Company-B). 'A clear project plan which everyone is working within / a plan that has been bought into. So, this is what we're going to do, this is why we're going to do it, this is how we're going to do it, this will be the outcome at this time. And if that level of clarity is there, it makes it much easier to manage the entire situation. The other area of R&D that is important … is that you have not only an eye on speed, i.e. bringing things through as quickly as possible, but also at the correct level of quality' (Company-C).	'Two things rather than a single thing: firstly, effective communication at all levels with people inside and outside the company, trying to keep everybody informed and trying to squeeze information out of people, and secondly allowing enough flexibility, i.e. managing the balance between trying to monitor and shape what is going on in research and giving people the creative flexibility they need. You can't manage research as tightly as you can manage development activities … you have to accept that there are going to be blind allies and backtrackings and sudden breakthroughs' (Company-G). 'Communication is probably key. Our Chief Executive says that we're not selling drugs, we're selling knowledge. And I think on every step of the way communication is the big thing' (Company-H).	A clear focus, an innovative approach, and strong defence of intellectual property are suggested by comments from Company-J and Company-K. 'It's pretty much a cliché isn't it, but it's the people. It's who you get together, and it's the management and the mix … Communication is key, which is fairly easy in a small environment. This may change as the company grows … the reality is that there is a strong motivation that you're actually doing something to help people' (Company-I).

PHARMACEUTICAL COMPANIES	BIOPHARMACEUTICAL COMPANIES	BIOTECHNOLOGY COMPANIES
Qu.26: What do you believe is the single most important factor in the successful management of R&D? – *Continued*		
'Project planning, risk management and above all communication are key tools for success' (Company-D). 'I think that the most important thing is the people side of things. The whole business revolves around teams of people. The task is far too big for any one individual or any one group now' (Company-A-1). 'Communication to all involved is an important part of the process' (Company-E). 'The increasing pressures from 'outside' on commercial viability is something that needs to be taken seriously because all the other stuff we'll focus on anyway. Everybody likes doing science here and all the other things, but if you don't focus on the commercial stuff you wont be in business very long' (Company-A-2).		